Report of the
National Commission on Diabetes
to the Congress of the United States

THE LONG-RANGE PLAN TO COMBAT DIABETES
1976 UPDATE

APPENDIX

U.S. Department of Health, Education, and Welfare
Public Health Service National Institutes of Health

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"The National Diabetes Mellitus Research and Education Act" (Public Law 93-354), signed by the President on July 23, 1974, directed the appointment of a National Commission on Diabetes, whose charge was to formulate a long-range plan of research and education to combat diabetes mellitus. The Commission submitted its report to Congress on December 10, 1975, and concluded its term on January 10, 1976.

The National Commission on Diabetes was reestablished on April 22, 1976, by enactment of Public Law 94-278, which extended its term through September 30, 1976. This 1976 update of the Commission's Report was submitted to Congress on November 30, 1976.

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Report of the
National Commission on Diabetes
to the Congress of the United States

THE LONG-RANGE PLAN TO COMBAT DIABETES
1976 UPDATE

APPENDIX

AMERICAN FOUNDATION FOR THE BLIND, INC.
15 WEST 16th STREET
NEW YORK, N. Y. 10011

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service National Institutes of Health

DHEW Publication No. (NIH) 77-1230

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APPENDIX A

DIABETES RESEARCH AND TRAINING CENTERS
ANNOUNCEMENT
AND
GUIDELINES

DIABETES RESEARCH AND TRAINING CENTERS

Announcement
and
Guidelines

National Institutes of Health
National Institute of Arthritis,
Metabolism, and Digestive Diseases

Bethesda, Maryland

DIABETES RESEARCH AND TRAINING CENTERS

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DIABETES RESEARCH AND TRAINING CENTERS

In 1974, the National Diabetes Mellitus Research and Education Act (PL 93-354), (42 USC 289c-2), authorized the Secretary of Health, Education, and Welfare to establish a number of Diabetes Research and Training Centers. This announcement provides for interested applicants a detailed description of the purposes of the Diabetes Research and Training Centers and a description of the applicable guidelines.

I. PURPOSE

The Diabetes Research and Training Centers (DRTC) are directed to conduct research and programs for training in diabetes mellitus and related endocrine and metabolic disorders consistent with the legislation and applicable recommendations made by the National Commission on Diabetes. Specifically, the National Diabetes Mellitus Research and Education Act charges each DRTC to conduct:

(A) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic disorders and the complications resulting from such disease or disorders,

(B) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such disease, disorders, and complications, and

(C) information programs for physicians and allied health personnel who provide primary care for patients with such disease, disorders, or complications.

It is the inclusion of the training and education efforts with the research program efforts that distinguishes the Diabetes Research and Training Centers from the presently supported Diabetes-Endocrinology Research Centers, which are specifically oriented to research goals. The National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) will, however, continue the Diabetes-Endocrinology Research Centers Program. Specific information regarding the program announcement and guidelines are available from the Institute.

II. GENERAL DESCRIPTION

In accordance with the guidelines proposed by the National Commission on Diabetes, a Diabetes Research and Training Center is charged with three principal functions:

1) performance of research into the cause, treatment, and management of diabetes,
2) training of professional personnel both for research in diabetes and for management of the diabetic, and
3) translation of advances in the field of research and improved methods of care into improved care for the diabetic patient.

Research Component

The Diabetes Research and Training Center grant provides a mechanism for fostering the interdisciplinary cooperation of a group of established investigators conducting high-quality programs aimed at increasing knowledge of the etiology, pathogenesis, and management of diabetes mellitus and related endocrine and metabolic diseases.

The intent of the NIAMDD in employing this mechanism is to build upon research activities and resources directed toward diabetes mellitus which are already developed and adequately supported on an individual project basis. While the NIAMDD will provide support for core resources, it is expected that the DRTC will obtain funding from other sources such as grants and contracts from the NIH and other Federal agencies, as well as support from organizations outside of the Federal government, including the voluntary health organizations.

"Core" support is thus intended to strengthen existing research programs, increase productivity, and foster generation of new ideas through collaboration among investigators and departments. As such, a DRTC grant provides an added dimension which includes capability and potential for a net accomplishment greater than that possible by the support of individual projects alone. In addition, the DRTC grant may include funds for the coordination of Center activities with other related NIH supported programs and for program enrichment (i.e., seminars, visiting scientists, etc.). It may also provide funds for feasibility and pilot research studies.

The research component of the DRTC may include any bona fide hypothesis-testing or careful systematic study or investigation undertaken to establish facts or principles related to the control and prevention of diabetes mellitus.

Since education is an integral component of treatment, research in diagnosis and treatment of diabetes may include research into educational methods and materials. Therefore, it is conceivable that the research program of a DRTC could include research into innovative educational approaches for the continuing education of health professionals, as well as the development of flexible curricula and appropriate materials tailored to the cultural background level of particular diabetic patients. Specific projects concerning the problem of psychological influences of the diabetic state can be included in the research component of the DRTC. In addition, a DRTC could include research projects directed toward development of new health care delivery systems for patients with diabetes or its related metabolic and endocrine disorders. The funds for the on-going support of these projects must be obtained from appropriate agencies, e.g., National Institute of Mental Health, Health Services Administration, American Diabetes Association, and Juvenile Diabetes Foundation.

In the recommendations of the National Commission on Diabetes, the "team" approach was recognized as being critical to management of the diabetic patient. It was judged desirable to utilize the skills of health professionals of all disciplines in all aspects of diabetic management, care, and education. As such, applicants may wish to develop projects in which the effectiveness of the "team" approach to the management of diabetes is examined.

The grant for the DRTC will provide support for core resources and core facilities. Funds will be available to the DRTC for feasibility and pilot studies and can be used to support any bona fide developmental research activity.

Training Component

Critical to an expanded national attack on diabetes mellitus is a pool of qualified health professionals needed to conduct research in diabetes and its management as well as a team of health professionals responsible for the care of the diabetic population. The generation of this manpower is considered to be an important function of each Diabetes Research and Training Center. As such, each DRTC will be expected to include the following activities:

1) training of postdoctoral fellows for research in diabetes and its management, and
2) the training of health professionals responsible for the care of the diabetic.

Each Diabetes Research and Training Center is expected to develop a research training program. As in the research component support through the DRTC will be limited to the core facilities; it will not include trainee stipends. NIH support for this purpose is limited to the National Research Service Awards. Research training at a DRTC will thus require, in addition to core center support, independent support for both research projects and fellows.

The Diabetes Research and Training Center is expected to play a key role in the generation of health professionals interested in diabetes and proficient in its management. The DRTC is expected to serve as the focal point within the educational programs of the parent university for training the full range of health professionals interested in diabetes. This range would include students in medicine, nursing, the allied health professions, interns and residents, and continuing education. The students themselves cannot be supported with DRTC grant funds.

Translation Component

A key function of the DRTC will be to translate results of research into health care practice. In order to foster rapid adoption of improved technology, a DRTC should initiate demonstration projects within the setting of the model patient demonstration unit which will be a focal point for the continuing education of health professionals (physicians and allied health personnel) in diabetes and its management.

Recognizing the importance of continued professional education in translating research knowledge into more effective health care for the diabetic patient, the DRTC grant may provide for the following activities within the Center:

a) Model Patient Care Demonstration Unit: This unit should function as a highly specialized resource for the education of health professionals and continuing education of practicing health professionals. It is not intended that the Demonstration Unit should undertake the responsibility for the care of diabetic patients; rather, patient care facilities will be those necessary for clinical research and for demonstration of new methods of treatment and care for the diabetic patient.

b) Medical Information Program: The DRTC could serve as a focal point for community efforts to analyze and disseminate information to health professionals for the prevention, diagnosis, and treatment of diabetes mellitus.

c) Educational Program: Educational activities will constitute an important segment of each DRTC. Some support can be expected to be available in the DRTC grant for support of a staff responsible for the development and evaluation of innovative educational programs for the health professionals. It is important that a DRTC educational program continually assess the effectiveness of the educational efforts. Support of these evaluative efforts can be provided in the DRTC.

d) Outreach Programs: The training and education functions of the Centers are intended to follow in two successive phases: (1) the earlier phase, in which emphasis is given to the training and education programs within the center as part of the national program; and (2) a later phase in which centers, once matured and having designed and evaluated training and education programs, begin to broaden their sphere of influence and effectiveness by developing outreach programs through cooperation, coordination and collaboration with relevant local, regional, state, and Federal agencies. In this case, the grant application should contain a statement of the long-range plans indicating how they will attempt to accomplish the development of outreach programs. Applicants who have already developed the earlier phase, should describe proposed outreach programs.

The development of continuing medical information programs, as well as the outreach program, must be based on a sound assessment of needs and on evaluation of program effectiveness emphasizing measurement of the behavioral changes on the part of the health professionals. Therefore, the DRTC should utilize the resources of various professional schools, the voluntary health agencies, the official health agencies, and the appropriate professional societies in carrying out this educational function.

III. ADMINISTRATIVE REQUIREMENTS

A Diabetes Research and Training Center shall be an identifiable organizational unit formed by a single university medical center or a consortium of co-operating institutions including the university-affiliated center. Such a center will of necessity involve the interaction of broad and diverse elements, and thus the lines of authority and sanction by the appropriate institutional officials must be clearly specified.

Each applicant institution will specify a DRTC Director. The DRTC Director will be the individual identified to be responsible for the organization and operation of the DRTC. The Director should be an experienced and respected individual, who can provide both scientific and administrative leadership for the total program. He must be able to coordinate, integrate and provide guidance in the establishment of new programs in research and allied areas.

An Associate Director should be named who will be involved in the administrative and scientific efforts of the project, and will serve as Acting DRTC Director in the absence of the Director.

It is expected that the DRTC administrative organization should encompass a supportive structure sufficient to insure accomplishment of the following:

1) coordinating and integrating the DRTC components and activities,
2) reviewing the utilization of funds for pilot and feasibility studies,
3) advising the DRTC Director on the activities of the Center.

While the final administrative structure of the DRTC will, for the most part, be left to the discretion of the applicant institution (subject to review by NIH peer review mechanisms), NIH's experience has demonstrated that the effective development of Centers programs requires interaction between the Center Director, the principal investigators, appropriate institutional administrative personnel, the staff of the awarding agency, and the members of the community in which the Center is located. Therefore, each Center applicant should establish an administrative structure which will permit the development of such interaction. At the same time, however, because funds for feasibility and pilot studies will be available, each applicant institution must establish a committee to review the use of these funds. This review committee comprised of Center investigators, outside reviewers, and consultants, will serve as the peer review function for the use of pilot and feasibility funds. In addition, this committee may review the overall activities of the DRTC. The mechanism for reviewing the use of the pilot and feasibility funds will be considered by the initial review groups in the evaluation of the DRTC application. The projects selected by the institutional review committee for the use of these funds will be described annually by the DRTC and will be given special attention by the Institute in its annual evaluation of the DRTC.

In order to assure active collaboration of the various DRTC programs with related interests, the DRTC Director may be asked to meet periodically with NIAMDD staff and with other Institute supported programs to review progress, to plan approaches for future investigations, and to share the accomplishments of the DRTC programs freely and openly. While each DRTC will be expected to develop its own program in accordance with local talents, interests, and resources, each must be responsive to national needs in diabetes, and must be willing to work with the NIAMDD and with other NIH-supported diabetes related programs in furthering overall goals.

IV. BUDGET

Unless otherwise indicated in the Notice of Grant Awarded, allowable costs under a grant are those permitted under the Federal Regulation applicable to that grant as amplified in the "Public Health Service Grant Policy Statement," the "DHEW Grants Administration Manual," and the appropriate cost principles. Overlapping support between DRTC core support and individual projects including research project grants, program project grants and contracts will be administratively reviewed, and if appropriate, will be adjusted to avoid duplication of funding.

Budget Categories

1. Personnel
   a. Professional

   This category may include support of salaries of key personnel within the DRTC who contribute to allowable activities of the Center. The salaries derived from the DRTC grant will depend on the effort provided and institutional salary policies. The DRTC Director is expected to devote a predominant proportion of his effort to the DRTC. The DRTC application should not include salaries for individual principal investigators on separate research or training projects unless they also provide an essential DRTC function.

   Salaries of professional personnel engaged in research activities supported by pilot and feasibility funds of the DRTC are an allowable cost item. The amount charged to the DRTC grant must be commensurate with the time spent on the DRTC grant supported project. Salary support derived from such activity should not extend beyond three years.

   b. Technical and Support Personnel

   This may include salaries for identified positions to be filled in the DRTC. No overlap of time or effort between the DRTC and separately-funded projects is permitted.

2. Equipment

Where large items of equipment are requested, the application must document those already available and provide clear justification in terms of use by investigators in several projects. General purpose equipment needs should be included and justified only after surveying the availability of such items within the institution.

3. Supplies

Consumable supplies directly related to the operational aspects of the DRTC are allowed. This includes office materials as well as scientific supplies but should not provide supplements to the general supply category of separately funded individual projects. If some supply items are to be provided to individual projects in order to effect a cost-saving, the respective supply budgets of individual projects should be appropriately reduced.

4. Research Patient Care Costs

Research patient care costs (both in-patient and out-patient expenses) will be considered in the context of other existing institutional clinical resources. Attempts should be made by the applicant institution to utilize existing clinical facilities, such as General Clinical Research Centers and individually supported beds. Costs relating to the clinical research efforts of either the DRTC or the participating projects may be funded through the DRTC provided there is no overlap of funding. Costs already budgeted in individual projects should be appropriately reduced if such costs are to be transferred to the DRTC budget. The DRTC is not intended to be a facility for health care delivery; thus, only those research patient costs directly related to the various research, education, and demonstration activities may be charged to the DRTC.

5. Alteration and Renovation

Funds for alteration and renovation of an existing structure to provide suitable core facilities for the DRTC may be made available from the grant under current PHS guidelines.

6. Travel

Domestic and foreign travel of project personnel directly related to the core activities of the DRTC is allowable. Travel of physicians and allied health personnel for attendance at DRTC educational activities is not allowable.

7. Consultants

Consultants and any associated costs (consultant fees, per diem, travel) may be included when their services are required within the DRTC.

8. Other expenses

Maintenance contracts on items of shared equipment within the DRTC, various charges not charged to individual projects, etc., may be included. Contracts with other institutions for research or services may be funded, but are considered consortium arrangements and must follow PHS policy.

Pilot and/or Feasibility Studies

In order to encourage investigators with diverse scientific expertise to work together in developing new studies and exploring the feasibility of possible new leads or pilot studies, a direct cost item for feasibility and pilot studies may be included in the DRTC grant application. The actual amounts allowable for this item will be in accordance with the recommendations of the initial review group of the NIH.

In all competing applications, applicant institutions should describe the specific projects and their budget for which feasibility funds are requested from the DRTC grant. These will be evaluated by the initial review group of the NIH. The evaluation will serve as a basis for establishing recommendations concerning the level of funds that will be awarded in this category during each year of the project period.

In subsequent years, the review committee established within the DRTC must insure the scientific quality of these research endeavors. Any additions or replacement projects supported by the pilot and feasibility funds must be reviewed and selected by the review committee. The projects will be described in the annual report, and Institute staff, Council members, and appropriate consultants will review and evaluate the use of pilot and feasibility funds on an annual basis.

Funds within this category may be budgeted into technical personnel, equipment, supplies and research patient care categories. Funds from the DRTC grant to support a pilot or feasibility study (or an investigator receiving such funds) will be limited to three years. Since the amount of funds in this category will be limited by the recommendations of the initial review group, investigators utilizing pilot and feasibility funds should be encouraged either to discontinue or to apply to the appropriate granting agency for support as soon as the feasibility of a project is determined.

Program Enrichment Funds

An amount of funds for DRTC enrichment purposes (e.g., special lectures, visiting professors, symposia, etc.) may be allowed when specifically described and the cost itemized. Such expenditures should be related directly to the DRTC and not to separately-funded projects.

While it is recognized that the DRTC will provide an environment for various training efforts, stipends for trainees are not an allowable charge to the DRTC. Postdoctoral research trainees may be supported by fellowships awarded under the auspices of the National Research Service Award Program or other available sources.

V. APPLICATION PROCESS

A. Pre-Application

The NIAMDD has been authorized by law to establish DRTCs, within the limits of available funding, to meet a national need. The dates for receipt of applications will be announced by the NIAMDD in the _Grant Supplement to the NIH Guide for Grants and Contracts_.

1. Pre-Application Conference

Consultation between NIAMDD staff and potential applicants prior to submission of the formal application is encouraged. To facilitate the initial implementation of the DRTC program, the Institute will hold a meeting in which representatives from interested institutions are invited to participate. The purpose of this is to describe the DRTC in more detail than is possible in these guidelines and to enable potential applicants to obtain clarifications and answers from staff.

2. Letter of Intent

In order to facilitate Institute planning, applicants are asked to submit to the NIAMDD a letter of intent describing their proposed DRTC. The letter should be limited to a brief description of the DRTC's emphasis, the main research studies, and the principal demonstration programs to be proposed. It should provide a statement of the existing applicable resources and proposed additions to be requested in the application, a list of key participants, and an estimate of the level of support required in direct costs.

Applicants should not construe advice given by the Extramural Program staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the proposal.

B. Application

The application procedure includes submission of a letter of intent and an application submitted to meet the respective receipt dates published in the announcement.

Currently funded Diabetes-Endocrinology Research Centers are eligible to apply for the DRTC program. Applicants should consult NIAMDD staff concerning the development of the DRTC application. In the event of funding of a new DRTC, the Diabetes-Endocrinology Research Center will be subsumed into the DRTC.

The original and six copies of the completed application should be mailed to the Division of Research Grants; addressed labels are included in the PHS Form 398 application kits. Two additional copies should be sent under separate cover to the Associate Director for Extramural Program Activities, National Institute for Arthritis, Metabolism, and Digestive Diseases, Westwood Building, Room 607, Bethesda, Maryland, 20014.

The Division of Research Grants has the responsibility of assigning an application to the appropriate NIH Institute. Applications not in accordance with DRTC guidelines will be returned to the applicant.

Applicants should keep in mind that the written application is the basis for the merit review. Particular attention should be paid to the format of the application. A detailed composite budget for all support requested for the first year should be included in the application immediately before the textual description of the DRTC proposal. Accompanying this should be a summary budget, by major category only, for each year of requested support. No more than five years of support should be requested. Separate descriptions and budgets should be submitted for each core facility, model demonstration unit, pilot study, etc.

The application should contain a description and fiscal summary of all relevant Center activities.

VI. REVIEW CRITERIA

The Diabetes Research and Training Centers application will be evaluated in national competition by the NIH grant application review process. Applications will be reviewed by a special programs review group of the NIAMDD and subsequently presented to the National Arthritis, Metabolism, and Digestive Diseases Advisory Council.

Major review factors, listed below, will be used in the evaluation of the DRTC applications.

A. Research

1. The scientific relevance, interrelation, and quality (as determined by the initial review group of the appropriate agency) of each of the separately funded research projects to the central theme of the DRTC and the likelihood for meaningful collaboration.

2. The qualifications, experience, and commitment of the investigators responsible for the individual research projects and their willingness to interrelate with the other elements of the DRTC.

3. The scientific merit of the pilot and feasibility projects for which funds are requested from the DRTC grant. Evaluation of the new research initiatives will serve as a basis of establishing recommendations concerning the level at which these activities will be supported throughout the project period.

B. Training

The applicant's activities for the generation of manpower necessary to conduct research in diabetes as well as health professionals responsible for the care of the diabetic.

C. Translation

The applicant's activity or planned activities in demonstration and professional education that would effectively translate research knowledge into improved health care for the patient.

D. General Considerations

In addition to the requirements previously described, assessment will be made of the applicant's capability to work with groups in Federal and private sectors having responsibilities for related aspects of diabetes (e.g., CDC, Health Systems Agencies, etc.). Consideration will be given to locating Centers geographically on the basis of population density.

E. Administration

1. The scientific and administrative leadership ability of the DRTC Director and the Associate Director and their commitment and ability to devote adequate time to the effective management of the DRTC program.

2. The proposed administrative organization necessary to conduct the following:

   a. Coordination of on-going research of both the separately funded projects and the DRTC. This will include various mechanisms for internal monitoring.

   b. Maintenance of internal communication and cooperation among the investigators involved in the program.

   c. Procedure for inclusion or termination of separately funded projects to be part of the DRTC program.

   d. Mechanism for selecting or replacing professional or technical personnel within the DRTC.

   e. Mechanism for reviewing the use of, and administering, funds for pilot and feasibility projects.

   f. Management capabilities that include fiscal administration, procurement, property and personnel management, planning, and budgeting, etc.

3. The appropriateness of the DRTC core budget and feasibility studies budget in relation to the total program.

4. The ability of the proposed DRTC to gain additional financial support for educational purposes from other Federal and non-federal sources.

F. Institutional Commitment

1. The institutional commitment to the program, including its lines of responsibility to the DRTC grant and the institution's contribution to the management capabilities of the DRTC.
2. The academic environment and resources in which the research will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.
3. The institutional commitment to new individuals responsible for conducting essential DRTC functions.

VII. REPORTING REQUIREMENTS AND ANNUAL EVALUATION

A progress report containing the following information should be submitted with the annual continuation application:

A. A programmatic description of the DRTC program which will include the project titles, principal investigators or key personnel, their percent efforts, budgets, description and progress of the DRTC-supported projects initiated during the budget period, all continuing DRTC-supported projects, and all DRTC-supported projects terminated during the budget period.

B. A description of all pilot and feasibility projects that received DRTC support during the budget period. The description of projects terminated during the period should contain an outline of significant results, publications and source of on-going support, if any. In newly initiated projects, a scientific description, budget and curriculum vitae of the investigator must be provided. In addition, a list of review committee members evaluating the project for DRTC support must be included.

C. A statement of the estimated use of funds. In conjunction with the programmatic description, this report will describe allocations in usual budget categories (i.e., personnel, equipment, travel, etc.), as well as the total expenditures for support of the following:

1. centralized and coordinating activities,
2. pilot and feasibility projects,
3. projects of principal investigators,
4. projects related to the DRTC but independently funded (non-DRTC support),
5. special enrichment activities (seminar speakers, visiting scientists, and consultants),
6. alterations, renovations, and equipment purchases,
7. model patient care demonstration unit(s),
8. information program(s), and
9. education program(s).

D. List of project titles, source of support, yearly budget, and percent efforts of all other non-DRTC-supported projects in which DRTC investigators participate.

E. A discussion of the effectiveness of the DRTC grant in furthering the goals of the DRTC program.

F. A discussion of any problems which impede accomplishment of the stated goals in the administration of the DRTC grant.

The expanded progress report does not replace other management reports required by PHS policy.

Evaluation

The National Diabetes Mellitus Act of 1974 "requires the Secretary [of DHEW] to evaluate on an annual basis the activities of the centers . . ." and "to report to the Congress . . . the results of his evaluation." The Director of the NIAMDD will assist in preparation of this report, and will refer to the annual progress report, as well as to any other documents that may be requested, which are used by the NIAMDD and its Advisory Committee in conducting an annual review of the progress and quality of the DRTC. Particular attention will be paid to assessing the progress made by the DRTC in fulfilling the purposes of the DRTC program. The program will be reviewed for accomplishment including contribution of individual investigators, significance of their research, adequacy of facilities, effectiveness of communication, use of pilot and feasibility funds and overall program productivity.

VIII. SPECIAL CONSIDERATIONS

It is to the benefit of both the NIAMDD and the grantee institution to assure that the Diabetes Research and Training Centers achieve and maintain the highest level of excellence and integrated effort. Therefore, the annual reports will serve to detail the fulfillment of the potential described in the initial application and award. However, in the event that major changes in the program occur, it may be necessary to have an interim site visit to discuss the changes and possible budget adjustments. Any changes in support level will require review by the National Arthritis, Metabolism, and Digestive Diseases Advisory Council.

Review of competing extension applications (renewals) should be completed at least one year prior to termination of the project period of the DRTC. Therefore, if a competing extension application does not successfully compete to continue as a DRTC, either because of scientific merit or change in emphasis, adequate time should exist either to find alternate types of support (i.e., individual research grants, non-government support) or to phase-out the effort. Additional time may be given for phase-out if funds for the last budget period can be better utilized in this manner to alleviate hardship to personnel, projects, or institution.

APPENDIX B

DIABETES HEALTH CARE, EDUCATION, AND CONTROL PROGRAM ACTIVITIES

WORKSHOP

on

MENTAL HEALTH

and

TREATMENT OF DIABETES

February 26, 1976

Sponsored by

the
National Institute of Arthritis,
Metabolism, and Digestive Diseases
in cooperation
with the
National Institute of Mental Health

WORKSHOP ON MENTAL HEALTH AND TREATMENT OF DIABETES

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INTRODUCTION

When the National Commission on Diabetes began its work and held public hearings in various parts of the country, individuals with diabetes and parents of children with diabetes expressed their concern for the emotional cost involved in living with this disease. Three Committees of the Commission concerned themselves with this subject as one part of their total responsibilities. The Workgroup on the Socioeconomic and Psychosocial Impact of Diabetes of the Committee on the Scope and Impact of Diabetes, the Committee on the Scope and Impact of Diabetes, identified and documented the needs in this area. The Committees on Treatment and on Education examined the state of the art of patient treatment and education and of professional education as it relates to this aspect of the total diabetes problem. The Report of the Workgroup on Resources also examined this area of concern in regard to better utilization of already existing resources and particular reference is made there to the National Institute of Mental Health.

Thus, as the Commission formulated its Report to Congress and outlined the extent of the problems related to diabetes, recognition was made of both the need for psychological counseling and for sound research in this area of therapy.

It is in response to these findings and recommendations that a Workshop on Mental Health and Treatment of Diabetes was sponsored by the National Institute of Arthritis, Metabolism, and Digestive Diseases with the cooperation of the National Institute of Mental Health.

DIABETES AND MENTAL ILLNESS-- SIMILAR PROBLEMS IN ACHIEVING TREATMENT GOALS

Louis E. Kopolow, M.D., Chairman

I consider it both an honor and an important opportunity to participate in this Workshop on Mental Illness and the Treatment of Diabetes. These two diseases, mental illness and diabetes, are not frequently linked by the public, government agencies, mental health professionals, or diabetologists. The similarities and common features shared by both impairments are, however, sufficiently widespread, that it is surprising that closer collaboration has not existed in the past between those concerned with the mentally ill and with the diabetics. Some of these common features of diabetes and mental illness worth noting are:

1. Both diabetes and mental illness are chronic diseases for which there is treatment but no known cure.
2. The incidences of mental illness diagnosed initially in medical settings and of diabetes mellitus in the population are the same (5 percent), (although the incidence of mental illness in the general population is closer to 15 percent) and there are significant numbers of people suffering simultaneously from both maladies.
3. Both illnesses require specific attention at the two extreme ends of the age spectrum. In the case of diabetes, juvenile diabetes in childhood and adult onset diabetes in later life, and in the case of mentally ill, childhood psychosis and autism and in the elderly organic brain syndrome.
4. Patients with either diagnosis suffer from discrimination and avoidance by the general public.
5. Environmental and social factors affect the exacerbation and prognosis in both diabetes and mental illness.

6. In both diabetes and mental illness a major problem exists in trying to provide adequate services to the nation, specifically in areas of:

    a) Sufficient trained personnel

    b) Adequate financial resources, and

    c) Public education.

With these common features in mind, the relevance of this workgroup becomes even more clear. There are, however, additional reasons why this is an auspicious time for a workgroup on Mental Illness and the Treatment of Diabetes to occur. Psychiatry, after many years of pulling away from general medicine, has recently begun to recognize the need to establish its ties with the other medical specialties. Such a trend is reflected in ADAMHA's increased participation with other institutes in the NIH. Interagency committees are seeking to coordinate research activities in the areas of heart, lung, blood vessel disease, and in this workshop today, on diabetes. In addition, there has been recent research revealing the marked interrelationship between mental health and diabetes treatment which will be dealt with more fully later this morning.

Congress has also recognized the need for community mental health centers to expand their involvement in what in the past have been medically related activities. Specifically, the CMHC Act of 1975, P.L. 94-63 requires that the CMHCs maintain a health status record, establish liaison activities with other health agencies, and appropriate specific sums for consultation and educational functions (monies which might potentially be used for developing programs geared to meeting the mental health needs of diabetics).

The recommendations made in the report of the Committee on Scope and Impact to the National Commission are extremely important. In the past, the lack of cooperation between mental health and the rest of medicine was viewed as merely unfortunate, but today, with the recognition of the interrelationship between emotional factors and physical illnesses, such an occurrence presents an intolerable situation.

It is hoped that the proceedings of this meeting, research findings discussed, and the recommendations made, would go a long way in remedying this problem and toward filling the imperative need for understanding the importance of the mental health component in the treatment of diabetes.

WORKSHOP PRESENTATIONS

Presentations were made by Dr. Lester Baker, Dr. David M. Holmes, Dr. Leonard S. Goldstein, and Dr. Jerry M. Wiener, summaries of which follow.

Dr. Baker presented studies being conducted under the auspices of Children's Hospital of Philadelphia, Child Guidance Clinic, Departments of Pediatrics and Psychiatry, University of Pennsylvania School of Medicine. His subject was "The Use of Beta-Adrenergic Blockade in the Treatment of Psychosomatic Aspects of Juvenile Diabetes Mellitus." This presentation was a means of demonstrating how a research project concerning the emotional health of patients with diabetes can be approached on as sound a scientific basis as can studies in a laboratory setting.

Appended is a paper which describes the study (published in _Advances in Beta-Adrenergic Blocking Therapy_, edited by Alan G. Snart, Vol. V, Princeton: Exerpta Medica, 1974).

Dr. Holmes emphasized the importance of a concern for the quality of life of individuals who must live with diabetes, and he presented a research study proposal which was designed for the purpose of "Meeting Psychosocial Needs of People with Growth Onset Diabetes."

Dr. Goldstein presented a review of the role of Community Mental Health Centers as a Federal contribution toward providing mental health services in the treatment of persons with diabetes

Dr. Wiener's presentation dealt with the needs for treating the emotional problems of diabetic patients from a non-federal viewpoint, and he emphasized an interdisciplinary multiple modality approach which would utilize primary, secondary, and tertiary professional care personnel as well as patient and family groups.

The use of beta-adrenergic blockade in the treatment of psychosomatic aspects of juvenile diabetes mellitus*

LESTER BAKER, SALVADOR MINUCHIN and BERNICE ROSMAN

Division of Metabolism, Children's Hospital of Philadelphia, Child Guidance Clinic, Departments of Pediatrics and Psychiatry, University of Pennsylvania School of Medicine, Philadelphia, Pa., U.S.A.

ABSTRACT

In the past several years our group has succeeded in defining a small group of children who were previously included in the general wastebasket of emotional disorders in diabetic children. For these children, emotional arousal directly and causally led to decompensation of their diabetic control, manifested as repeated bouts of ketoacidosis (not explicable on any organic basis), necessitating either frequent hospitalizations or a major loss of school time. For these children, then, recurrent bouts of diabetic acidosis represented a psychosomatic disease. In an early series of studies it was shown that catecholamines appeared to be the major factor in the mediation of emotional arousal to diabetic acidosis. The pathway was viewed as: emotional arousal → autonomic nervous system activation → excessive and prolonged lipolysis → increased free fatty acid concentration → excessive production of ketone bodies by the liver → diabetic ketoacidosis. These studies also led to the use of β-adrenergic blocking agents as part of the therapy for these children, and this approach appeared to be quite successful.

We have now treated 19 children classified as having a major psychosomatic component to their diabetic control. The overall success rate of β-adrenergic blockade therapy in this type of patient has been 89%. Recently, we have studied 7 patients in a prospective manner, designed to test certain hypotheses which might allow us to predict the effectiveness of β-adrenergic blockade therapy in specific patients. These hypotheses were based upon a logical model in which the development of ketoacidosis could be viewed as problems of 'turn-on' and/or 'turn-off'. These specific areas could be examined in each individual patient in both physiological and psychological terms. No evidence of innate physiological hyperlability was seen in the psychosomatic group: changes in free fatty acid concentration in a neutral environment, and following a low dose isoproterenol infusion, were not significantly different in this group, when compared to a contrast group of diabetic children. Significant differences, however, were demonstrated in the free fatty acid response to a standardized family

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* Supported by Public Health Service Grants No. MH 21336 and AM 13518. The studies were carried out in part in the Clinical Research Center of the Children's Hospital of Philadelphia, supported by the National Institutes of Health Grant No. RR 00240.

diagnostic stress interview. The psychosomatic group demonstrated a significantly greater 'turn-on' than the contrast group, but a more significant defect in 'turn-off' was seen in the psychosomatic group. This impairment in 'turn-off' could be correlated with the psychological characteristics of family interaction, and more specifically, with the role of the child in family conflict. These latter hypotheses have been put together into a conceptual model of the 'psychosomatogenic family'. Knowledge of an individual child's pattern of 'turn-on' and 'turn-off' was used to predict the efficacy of β-adrenergic blockade; the correlation between prediction and actual clinical course was good in 6 of the 7 patients. Based upon these studies and observations, the following conclusions may be drawn:

1. Diabetic acidosis can represent a true psychosomatic disease in a small number of children. This disease can now be diagnosed in a positive way, not merely by ruling out other causes for diabetic hyperlability.

2. Beta-adrenergic blockade is an effective form of adjunct therapy in these children. It appears possible to set up criteria which will allow one to predict the efficacy of β-blockade therapy in an individual patient.

3. Study of this disease has given rise to a new conceptual model of psychosomatic disease in children, focused about the idea of the 'psychosomatogenic family'.

In 1969 our group published the first paper (Baker et al., 1969) concerning the use of β-adrenergic blockade in patients with juvenile onset diabetes mellitus who were repeatedly hospitalized because of diabetic acidosis. The first several children in whom this therapy was attempted benefited dramatically, with a cessation or marked reduction in the number of hospital admissions. However, a much wider experience in the use of β-adrenergic blockade in such patients has caused us to re-examine this whole area. Specifically, the failure of β-adrenergic blockade therapy to 'cure' all such patients has led to investigations seeking to examine the following questions:

1. In which group of juvenile diabetics should one consider the use of β-adrenergic blocking agents?
2. Are there predictive tools which will help decide whether β-adrenergic blockade will be effective in any given patient?
3. If repeated bouts of diabetic acidosis in these children can be viewed as a psychosomatic disease, i.e. emotional arousal directly causing a somatic and metabolic derangement, can one then use this as a suitable model from which to gain insights into the whole area of psychosomatic problems in paediatrics, with particular reference to the interplay of disease, index child, and family?

Our interest in this area was initially kindled by the referral to our Medical Center of children who were literally 'crippled' by their diabetes, in that multiple hospitalizations were required for the treatment of life-threatening diabetic acidosis. Figure 1 shows the typical course of 2 such patients who were studied early in this series. As can be seen, they were each hospitalized approximately once every 3–4 weeks. No organic cause for this excessive instability or brittleness could be found, despite exhaustive search along the lines suggested by Molnar (1967), as seen in Table I. After one looks for possible sources of patient or physician error, and assesses the possibility of endocrine, hepatic, or inflammatory causation, one is left with a large wastebasket termed 'psychological' or 'psychiatric' influences. Put in another way, as Molnar (1967) has done in Table II, of the various possible pathogenetic bases for 'brittleness', one is often left with a broad and poorly defined category of 'psychoneuroendocrine dysfunction'.

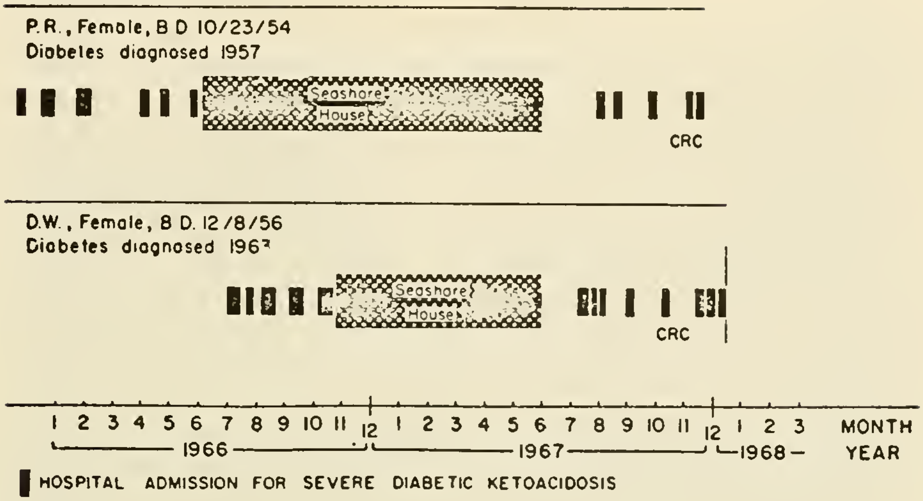

Fig. 1

The literature offers few insights into the effect of psychological or psychiatric influences on repeated bouts of ketoacidosis. Indeed, there are 2 opposite camps: such authors as Hinkle and Wolf (1952) have stated that the emotional state of the patient directly triggers the episodes of ketoacidosis, whereas Stearns (1959), in a paper

TABLE I

Avoidable or treatable causes of diabetic instability

I. Therapeutic errors
  1. Erratic timing of any or all therapeutic events
  2. Acute or chronic insulin overdosage
  3. Erroneous estimate of the duration of insulin action
  4. Faulty technique of insulin injection
  5. Dietetic errors or neglect
  6. Neglect or faulty appreciation of effects of muscular exercise
  7. Negligent or faulty testing for urinary glucose and ketone bodies
  8. Abnormalities of the renal threshold for glucose (high or low)
  9. Incomplete emptying of the urinary bladder
  10. Uses and abuses of therapeutic agents such as steroids and diuretics

II. Coexisting conditions
  1. Endocrine effects
    (*a*) Hypofunction of pituitary or adrenal
    (*b*) Hyperfunction of thyroid
    (*c*) Menstrual cyclic changes
    (*d*) Pregnancy
  2. Associated acquired or congenital non-endocrine diseases (such as hepatic, cardiac, renal, neurological, inflammatory, infectious) and neoplastic and traumatic conditions
  3. Psychological or psychiatric influences

(Reproduced from Molnar, 1967, by permission of the American Diabetes Association.)

TABLE II

Possible pathogenetic bases for 'brittleness'

1. Variable dynamics of circulating or tissue antagonists or antibodies to insulin
2. Variable, excessive hepatic sensitivity to insulin
3. Hepatoperipheral incoordination of tissue sensitivity to insulin
4. Variable, but generally excessive, fat mobilization under genetic, neuroendocrine, growth hormone, epinephrine, or mixed influences
5. Glucagon excess or deficiency
6. Psychoneuroendocrine dysfunction

(Reproduced from Molnar, 1967, by permission of the American Diabetes Association.)

appropriately entitled *Self-Destructive Behavior in Young Patients with Diabetes Mellitus*, concluded that emotions worked as secondary factors, leading to abandonment of the diabetic regimen, and thus the resultant ketoacidosis. In order, then, to be more precise about the relationship between psyche and soma in diabetes, we have set up a tentative classification system of diabetes and emotions. In this system (Table III) the major distinction is between the psychosomatic and the non-psychosomatic groups. The non-psychosomatic group includes children with emotional problems related to the onset of diabetes, as well as those children whose emotional problems are really unrelated to the diabetes, but which may occasionally spill over into the areas of diabetic management. The classification is made on the basis of therapeutic implications, as well as on the presenting symptom. Thus, the child who has recurrent diabetic acidosis ultimately documented to be due to deliberate omission of insulin is considered to have an obvious emotional problem, but is placed in the non-psychosomatic category. Although his presenting picture may be quite similar to that of the psychosomatic diabetic, the relationship of emotions to diabetes and the therapeutic implications deserve a separate classification.

We feel that there exists a definable small group of children, previously included in the general wastebasket of emotional disorders of diabetic children, who can now be classified separately as having a true psychosomatic problem. For these children, emotional arousal directly and causally leads to decompensation of their diabetic

TABLE III

Diabetes and emotions: an abbreviated classification system

I. Non-psychosomatic
    A. Emotional disturbances associated with onset of diabetes
        1. Idiogenic
        2. Iatrogenic
    B. Emotional disturbances not associated with onset of diabetes
        1. Behavioural problems without metabolic consequences
        2. Manipulation of illness causing metabolic problems
II. Psychosomatic: Emotional difficulties cause metabolic derangements
    A. Recurrent ketoacidosis with frequent hospitalizations not due to any organic cause
    B. Chronic nausea and vomiting associated with acetonuria, causing repeated absences from school

control, manifested as repeated bouts of ketoacidosis, not explicable on any organic basis, necessitating either frequent hospitalization or a major loss of school time. There are the 2 clinical observations which raise the possibility that a child may have a psychosomatic problem. The size of the hospital chart is often an immediate clue, since several of these children have been in hospitals as frequently as once every 2–3 weeks. Another clinical observation has been the contrast between the lability of diabetic control of the child in hospital and at home. At home, these children will often proceed into diabetic acidosis despite large amounts of supplemental insulin; in hospital, modest amounts of insulin are often sufficient to reverse the ketoacidosis. During prolonged hospitalizations, either in an acute care hospital or in an extended care facility, diabetic control is relatively easy to attain. Return to the home situation, however, is almost invariably associated with the return to the preceding pattern of frequent bouts of unexplained ketoacidosis. These are the children who previously were noted to benefit by so-called 'parentectomy'.

We have reserved the use of β-adrenergic blockade therapy for only that group of diabetic children in whom a major psychosomatic component exists. Studies cited in our early paper (Baker et al., 1969) and subsequent unpublished observations provide data which warrant the conclusion that catecholamines play a major role in the mediation of emotional arousal to diabetic acidosis. The pathway is viewed as: emotional arousal → autonomic nervous system activation → excessive and prolonged lipolysis → increased free fatty acid concentration → excessive production of ketone bodies by the liver → diabetic ketoacidosis. This, the therapeutic introduction of β-adrenergic blockade in order to prevent excessive and prolonged lipolysis appeared a logical step, and, as mentioned, the first several patients were greatly benefited by this form of treatment. We have now treated 21 patients. While the overall success rate has continued to give us encouragement, the failure of β-adrenergic blockade therapy to 'cure' all patients with psychosomatic problems, plus the observation as is shown in Figure 2 that structural family therapy alone can be used to successfully treat this problem, has led us to an exploration of the variables in individual patients and to studies of how the family can affect the disease state. It has been possible to do this through a new conceptual model.

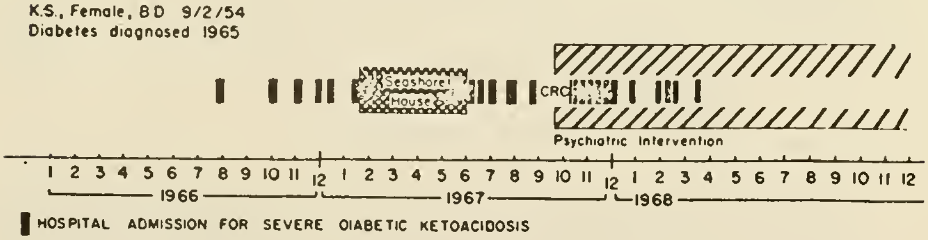

Fig. 2

The generally used linear model of psychosomatic disease is shown in oversimplified form in Figure 3. This model implies that the disease is contained within the affected individual, and that external inputs, as suggested by the word 'stress', are mediated through the individual's perception, his personality, his defences and coping mechanisms, etc. Therapy in this model allows for individual psychodynamic approaches,

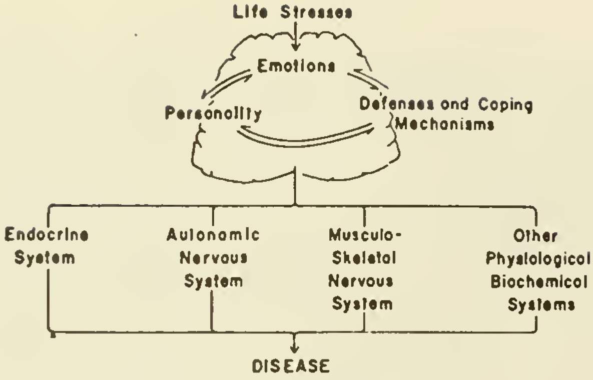
Life Stresses
Emotions
Personality
Defenses and Coping Mechanisms
Endocrine System
Autonomic Nervous System
Musculo-Skeletal Nervous System
Other Physiological Biochemical Systems
DISEASE

Fig. 3. Linear model of psychosomatic disease.

designed to attain greater insights, to strengthen coping mechanisms, or other similar techniques; or, more recently, the behavioural modification approach has sought to 'relearn' physiological mechanisms which have 'maladapted' and have caused the psychosomatic symptom. For paediatricians this model is insufficient, in that the role of the family is not taken into account in the initiation and continued expression of the psychosomatic symptom.

In working with these diabetic children, an open systems model of psychosomatic disease was formulated (Minuchin et al., 1974). It is shown graphically in Figure 4. Feedback loops are present at several key points: it appears that certain characteristics of family interaction are important in the mediation of a vulnerable child to a symptomatic one, and the symptomatic child appears to be important in maintaining the family homeostasis, which may account for the continuation of the symptom.

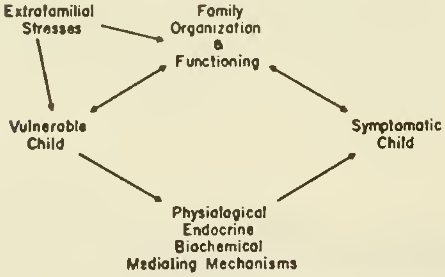
Extrafamilial Stresses
Family Organization & Functioning
Vulnerable Child
Symptomatic Child
Physiological Endocrine Biochemical Mediating Mechanisms

Fig. 4. Open systems model of psychosomatic disease.

The use of the open systems model has allowed us to set up several hypotheses which can be prospectively tested. One can look at the vulnerable child, for example, to see whether there are physiological differences between the psychosomatic group and other diabetic children. One can logically look upon the development of the psychosomatic crisis as an event which must consist of at least 2 phases: (1) a triggering, or arousing situation, and the individual response thereto, the so-called 'turn-on' phase; (2) a return to homeostatic and baseline levels, or what might be termed the 'turn-off' phase. These areas can be examined in each individual patient in both physiological and psychological terms.

To evaluate physiological problems concerning 'turn-on', 2 major studies were performed. As in most of our metabolic studies in diabetic patients, the child was admitted to the Clinical Research Center, acclimatized to his environment, long-acting insulin was withdrawn, and the child was maintained on doses of short-acting insulin given at meal times and before a late evening snack. Studies were performed at 8.00 a.m., with no insulin and no breakfast given on the study date. A small needle was inserted into a peripheral vein with a stopcock arrangement to allow for frequent blood sampling.

The first approach was to assess the child's 'endogenous' lability in a neutral environment. He is allowed to read, watch television, and otherwise engage in non-stimulatory types of activity. A single nurse is assigned to that child, and he is screened from other activities on the metabolic ward. Specimens for free fatty acid concentration are obtained every 30 minutes for a period of several hours. As can be seen in Figure 5, there are no differences in the free fatty acids curves in these children, when one compares the psychosomatic group vs. 2 control groups of diabetic children; diabetic children with behavioural types of emotional problems, and 'normal' diabetic children.

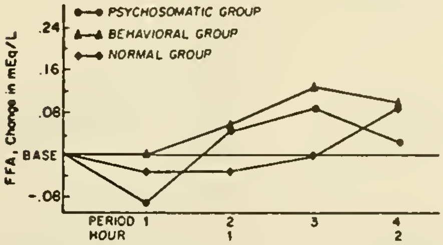

Fig. 5

To complement this assessment of endogenous lability, the child's response to an exogenous β-stimulatory agent was studied. Isoproterenol was infused at the low dose of 0.033 μg/kg/minute for 15 minutes. This dose is similar to that used in adults in studies of the 'hyperdynamic β-adrenergic circulatory state' (Frohlich et al., 1969). Free fatty acid concentrations were measured to establish basal levels, response to the isoproterenol, and the ability of the patient to return towards baseline levels following cessation of the infusion. These data are presented in Figure 6, which once again indicates that the psychosomatic group is no different in terms of both 'turn-on' and ability to 'turn-off' from the other control groups of diabetic children.

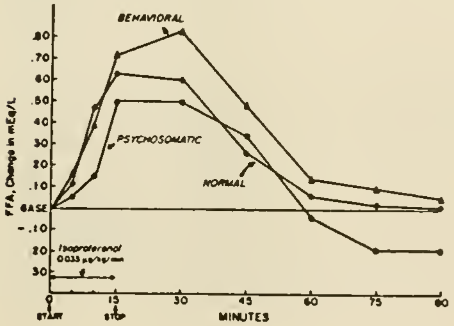

Fig. 6

The 2 studies cited above give no evidence of innate physiological hyperlability in the psychosomatic group. It is quite possible that these 2 studies do not really answer the question of whether individual overresponsiveness may play a role in the clinical problem, since the stimuli chosen were quite arbitrary, and may be far wide of the physiological mark. In an attempt to get closer to this problem, we have looked at the changes in free fatty acid concentration in these children during a structured family interview. In this, they would be responding to idiogenic family conflicts. The outline of the standardized family diagnostic interview is shown in Table IV. As can be seen, an attempt is made to elicit and intensify spouse conflict. This allows for stress which is idiosyncratic to that individual family to emerge. Psychiatric intervention is kept to an absolute minimum; this allows for more standardization, and thus allows for family-to-family comparisons. Free fatty acid concentrations are measured during this interview and Figure 7 shows a scene from one of these diagnostic interviews, showing the unobtrusive manner in which the specimens can be obtained.

TABLE IV

Outline of standardized family interview

Time	Phase			
8 a.m.				Insertion of I.V.
8.30–9	I.	Equilibration (specimens every 15 min)		Parents are settled in interview room, child in observation room behind one-way mirror
9–10.30	II.	Diagnostic interview (specimens every 15 min)		Structured interview designed to explore family's handling of idiogenic conflicts
9–9.30		Stage 1.	Conflict induction	Psychiatrist tells parents to discuss a family problem and leaves
9.30–10		Stage 2.	Induction of spouse conflict	Psychiatrist returns and allies himself with one spouse against the other
10–10.30		Stage 3.	Inclusion of child	Psychiatrist brings child into interview room and tells parents and child to help each other decide how they should change
10.30–12	III.	Recovery period (specimens every 30 min)		Family goes to same room. No medical personnel are present
12 noon		Debriefing		Interviewer and paediatrician meet with family to answer questions. If therapy is indicated or requested, family meets therapist

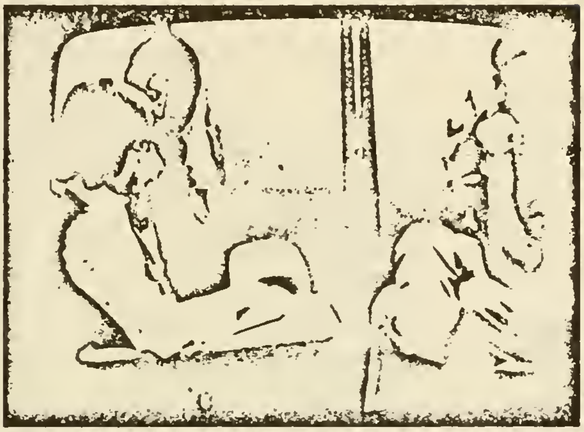

Fig. 7

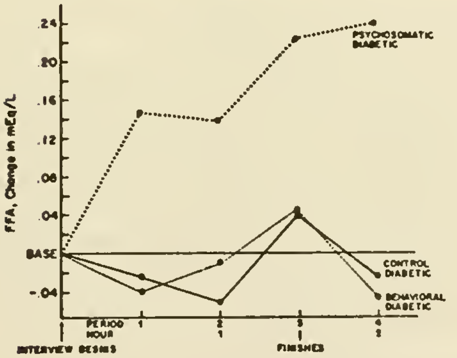

Fig. 8

Figure 8 shows the free fatty acid responses of the children to the standardized diagnostic family stress interview. The psychosomatic group demonstrates a significantly greater 'turn-on' than the contrast groups, with an equally significant defect in 'turn-off'. Thus, the impairment in 'turn-off' can be correlated with the role of the child in family conflict; that is, whether or not the child experiences difficulty in turn-off is directly related to his role in family conflict. In this view, there are certain situations in which the child is used in family conflict which will handicap turn-off; these are the patterns which characterize the 'psychosomatogenic family'. Thus, Figure 8 gives one of the first pieces of evidence that the family ecology is critical in determining physiological responses to a given stimulus.

We are just now completing this prospective study, having studied 7 families in which there is a diabetic child with a major psychosomatic problem, comparing them to 8 families in which there is a normal diabetic child, and 8 families in which there is a diabetic child with an emotional disturbance expressed in behavioural terms. The scoring of enmeshment, rigidity, overprotectiveness and lack of conflict resolution has not been completely made as yet; the preliminary data are quite encouraging and supportive of the conceptual model. It is also worth noting that therapy based upon

TABLE V

Prediction of effectiveness of β-adrenergic blockade in psychosomatic diabetic group

Child	Excessive 'turn-on'	Impaired 'turn-off'	Prediction	Correlation with observed clinical course
D. Coo	No	Yes	No response	+
S. Sto	No	Yes	No response	+
S. Stau	Yes	Yes	Moderate improvement	+
J. Re	Yes	Yes	Moderate improvement	+
L. Ree	Yes	No	Good response	+
C. Vic	Yes	Yes	Moderate improvement	–

this model has been extremely successful in aiding these children, and thus also gives indirect evidence in support of the validity of the conceptual model.

Although the psychosomatic group was clearly different in both its turn-on and turn-off groups, there was, as in all biological systems, a great deal of individual variability. Knowledge of an individual child's pattern of turn-on and turn-off was used to see if this would predict the efficacy of β-adrenergic blockade. It was reasoned that β-adrenergic blockade would be most helpful in those children in whom excessive turn-on was the dominant factor, and least effective when family interactions appeared to hamper 'turn-off'. The data are still preliminary, and the numbers are small (Table V). However, the correlation between prediction and actual clinical course was good in 6 of the 7 patients.

Based upon these studies and observations, the following preliminary conclusions may be drawn:

1. Recurrent diabetic acidosis without any organic explanation represents a true psychosomatic disease in a small number of children.

2. Beta-adrenergic blockade may be an effective form of adjunct therapy in these children. It appears possible to set up criteria which will allow one to predict the efficacy of β-blockade therapy in a given individual patient. In clinical terms it appears to work best in that group of psychosomatic children who present with recurrent bouts of acidosis which are not severe enough to warrant repeated hospitalizations (i.e., those children who respond to supplemental insulin given at home), but who nevertheless are sick enough to miss many schooldays.

3. Study of this disease has given rise to an open systems conceptual model for psychosomatic disease in children. This model focuses around the characteristics of a 'psychosomatogenic family', and the role of the child in family conflict. This model would appear to have great applicability to many other psychosomatic diseases in childhood.

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A Model for Mental Health-Behavioral Science Staff and Program, Including Federally Supported Research on Diabetes,

by David M. Holmes, M.D.

THE JOSLIN CLINIC: MEETING PSYCHOSOCIAL NEEDS OF PEOPLE WITH GROWTH ONSET DIABETES

Background:

Over more than half a century, the basic medical team of the Joslin Clinic has been a physician-nurse team, with the physician-diabetologist personally directing all aspects of treatment, and the nurse functioning in the role of assistant.

In the pre-insulin and early insulin eras, diabetic children lacked energy to keep up with non-diabetic children. Dr. Elliott Joslin's awareness of their individual and social needs showed up in his relationships with them, in his emphasis on the importance of pets, and in the character of the programs he developed. He drew Dr. Priscilla White to the staff. Aware of the inner, subjective, as well as social needs of patients, she has been able to maintain extraordinarily helpful relationships with an increasing number of growth onset patients, following some of them for over fifty years. All Joslin physicians maintained one to one relationships with their patients whenever possible. Since the importance of continuity of care can hardly be overestimated, in this regard, as in many others, the Joslin Clinic continues to provide a model for other health care systems. While trying to keep diabetic children alive was a consuming endeavor in the pre-insulin era, the inauguration of the summer camp program for diabetic children at the Clara Barton Birthplace in the 1920's, before the discovery of insulin, illustrates the dual thrust still characteristic of Joslin Foundation programs: to prolong life without losing sight of the inner, subjective and social aspects of experience that make life worth living.

Over the past twenty years, the Foundation has invited five psychiatrists or psychiatrists-in-training to participate in clinical, educational, and research activities. These physicians have worked closely with the New England Deaconness Hospital social workers who spend part of their time working with Joslin patients, especially inpatients. This collaboration has helped many patients with emotional and developmental problems, has encouraged publication on these aspects of diabetes, led in 1975 to the formulation of a study group on emotional and developmental aspects of diabetes, and now leads to the writing of this review and proposal. Subjects pursued in the study group include phenomenology of hypoglycemia, diabetes in girls and young women, self-image of diabetics _vs_ non-diabetics, psychological mechanisms underlying mismanagement, and patterns of psychiatric referral at the Joslin Clinic. Questions formulated for future study include subjective clues to hypoglycemia, psychological mechanisms underlying mismanagement in girls _vs_ boys, effect of continuity of care in preventing psychosis in Joslin patients, influence of health care team on family and

and individual mechanisms for dealing with diabetes, influence of family on psychological mechanisms used by diabetic, and the family in the first year following diagnosis of diabetes in a member. Since 1971, Dr. Holmes has consulted with about seventy patients a year, has provided about six hours of treatment a week for Joslin Clinic outpatients, and has provided non-clinical consultation to the Youth Division, the Youth Committee, the seminar and study groups on emotional aspects of diabetes, and members of these various groups. He has been remunerated for his time directly by patients or by their insurance in about a tenth of the 105 hours of inpatient consultation each year and for about half of the 270 annual outpatient treatment hours. Since 1971, the Foundation has paid $5,000 a year for the remaining 230 hours of his clinical and 75 hours of his non-clinical consultation time each year.

Finally, in 1972, the Youth Division catalyzed the formation of the Youth Committee, with about two hundred growth onset diabetic members, ages 15-30. In the first three years of its evolution, three significant purposes have already emerged: to help young diabetics form a cohesive, self-respecting group with its own leaders, able to formulate goals of common interest toward which the group works; to give young diabetics more opportunity to develop enjoyable, self-respecting relationships with other young diabetics; and to increase their understanding of diabetes and of themselves as diabetics. Goals of common interest have turned out to include trying to help disadvantaged diabetics through the Winter Camp program, organizing discussions of diabetes, marriage, and childbirth, organizing weekly discussion groups for patients in the Diabetes Treatment Unit, and raising money to become a self-supporting organization. Goals mentioned, but not yet attained include helping certain young diabetics through a Big-Brother, Big-Sister program, discussing relationships with parents and parenthood, and raising money for research.

Range of Options:

The Joslin physicians may choose to continue to try to meet their patients' psychosocial needs personally, directing psychosocial aspects of each patient's treatment. In this case part-time consulting services by a psychiatrist and New England Deaconess Hospital social workers would continue to provide some help to the primary physicians. As an alternative, Joslin physicians may choose to supplement these efforts by increasing mental health-behavioral science staff and programs. There are three factors which make it an advantage to move in this direction. First, it seems to be impossible for the best-trained physician, working 12 hours a day, six days a week, to meet all the medical plus psychological plus social needs of all his patients. Second, although third party payments for psychological services will increase significantly in January, 1976, as required by Massachusetts law, it would be more costly to the Clinic to pay physicians to provide the bulk of the services than to pay social workers and a psychologist. Last, a larger behavioral science presence is needed to develop and sustain certain social and preventive programs and to significantly increase new knowledge of emotional and developmental aspects of diabetes.

Ultimately the Joslin complex could use the services of up to six full-time clinical staff plus up to 29 hours a week of consultant time. These people should be recruited carefully over a period of about three years. All consultants and the supervisory social worker should be innovative, experienced, able to recruit and help younger professional people develop new skills and able to work with Joslin physicians to develop effective, useful clinical, educational and research programs. Ultimately, staff, working primarily with outpatients, might expand as follows:

POSITIONS	FUNCTIONS	Estimated Annual Cost to Insurance Carriers and Patients for Stipends
1 psychiatric consultant (8 hrs./wk.), part-time social workers ⟶ up to 6 consultants (29 hrs./wk.), 6 full-time clinical staff, and 3 clerk/secretaries	Limited effort ⟶ further development in four areas: 1. Clinical Services: a. Individual and family treatment programs; b. Social programs, to improve diabetes management, prevent social disability, and increase the quality of life, e.g., camps and Youth Committee. 2. Knowledge of emotional and developmental aspects of diabetes increased through clinical and experimental studies, leading to increased publication in this area.	$ 5,000 ⟶ up to $160,500

FUNCTIONS (Cont'd)

3. Education:

   a. of physicians, nurses, social workers, psychologists, and youth workers who come to the Clinic to learn about treatment of diabetes and about developing programs to help diabetics;
   b. of patients and families, some of whom can use information on emotional aspects of diabetes to minimize developmental difficulties.

4. Psychosocial programs evaluated, with flow of information to staff overseeing, designing, and implementing programs in three areas above.

BREAKDOWN OF POSITIONS	FUNCTIONS	Estimated Annual Stipend From Joslin Foundation
1 or 2 psychiatric consultants (adolescents-adult)	Participate in planning and development (3 hrs./wk.), provide supervision (4 hrs./wk.) group therapy (2 hrs./wk.), diagnostics (2 hrs./wk.), individual treatment (6 hrs./wk.), study, writing, research (2 hrs./wk.) Total: 8 up to 19 hrs./wk.	$ 5,000 ⟶ $ 30,500
1 psychiatric consultant (child-adolescent)	Participate in planning & development (1 hr./wk.), provide supervision (2 hrs./wk.), diagnostics (1 hr./wk.), study, writing, research (2 hrs./wk.) Total: up to 6 hrs./wk.	$ 0 ⟶ $ 12,800
2 or more consultants (might be psychiatrists, psychologists, social workers, nurses, or other disciplines)	Supervise "structural" family treatment, behavior modification, consult on research Total: up to 4 hrs./wk.	$ 0 ⟶ $ 6,200

BREAKDOWN OF POSITIONS	FUNCTIONS	Estimated Annual Stipend from Joslin Foundation
1 psychiatric social work supervisor (full-time)	Recruit & supervise social workers, participate in developing clinical, teaching and possible research programs	$ 16,000
3 social workers	Clinical work, both 1:1 and group, primarily with families and out-patients; one trained in child development, family structure, and family intervention could initiate a program to prevent developmental difficulties through home visits, relationships with family members, and provision of concrete assistance. Certain at risk groups could be identified and treated with group therapy.	$ 39,000 ($13,000 x 3)
1 Psychologist (probably clinical, starting half or full-time, ultimately full-time)	Behavior therapy, supervision, research, education	$ 9,500 (HT) 19,000 (FT)
Youth Worker (social organizer) starting half or full-time, ultimately full-time	Facilitate further development of groups of diabetics, to improve diabetes management, prevent social disability, and increase the quality of life.	$ 11,500
1 secretary, 2 clerk/typists	Clinical, research, educational program support	$ 25,500 ($9,500 (1) $8,000 x 2)

Projected annual cost of mental health-behavioral science stipends:

1975:	$ 5,000
1976:	69,000
1977:	105,000
1978:	160,000

THE ROLE OF MENTAL HEALTH SERVICES IN THE TREATMENT OF PERSONS WITH DIABETES

Leonard S. Goldstein, M.D.

The objective of developing a coordinated health services system for individuals with diabetes is both highly desirable and difficult. In a sense this effort parallels movement in the health services field towards better interdigitation of health services, greater interdisciplinary collaboration (among various health and mental health areas), and interprofessional collaboration. It is exciting to take part in an effort which could lead to the long elusive product of synthesis between research, training, services, and the development of a truly comprehensive health services model.

I have been asked to present a brief description of the kinds of mental health services available for the treatment of patients with diabetes and the mechanisms available for delivering such services. I will restrict my comments to the type of input Community Mental Health Centers (CMHC) might have, although services are available in other settings. One advantage of utilizing CMHCs in any service effort is that they represent a national program and consequently are highly available currently to over 40 percent of the total U.S. population. In July, 1975 the United States Congress passed P.L. 94-63, a new community mental health center law, to help complete the goal of a nationwide network of CMHCs as well as to insure comprehensive, high quality services. I shall discuss the new law later in my remarks, but first I will give a brief overview of the federally funded CMHC program.

The first community mental health center act was passed in 1963 to offer "seed grants" to every community in the United States. Soon after P.L. 88-164 was passed in 1963, States began adopting the new approach emanating from Federal policy. At present, there are 38 States in which community mental health laws have been passed to promote community care rather than asylums.

Community mental health centers have become extremely valuable resources in hundreds of communities. There are now over 540 operational community mental health centers in the United States, serving approximately 80 million Americans. These 540 community mental health centers serve approximately 140 communities in rural or semi-rural catchment areas, and 40 percent of all community mental health centers serve poverty catchment areas. Over one-third of the population of the United States now have community mental health center programs available to them. In 1974, community mental health centers provided care for 1,700,000 persons in their own communities. We are likely to see a continued rise in community health alternatives and community mental health programs. Thus, many health services will tend to be integrated with the community system to improve continuity of care.

I shall now briefly enumerate some of the achievements we have seen over the last decade in community mental health center programs. Some of these general achievements include the following:

> The development of sound theoretical and practical models to facilitate ACCESSIBILITY of mental health services to all socio-economic strata and geographical areas of the country.

Dramatic improvements in the more equitable distribution of mental health manpower.

Highly structured coordination of pre-existing community resources to assure continuity of care and cost efficiency hitherto unapproached.

Significant alternatives to institutional care, thus offering mental health clients a treatment based on what is optimal, rather than simply on what is available.

Continued and intensive thinking about how to curtail the cost of health services.

Providing a total treatment program that encompasses not just inpatient and outpatient services, but also partial hospitalization, emergency care, and consultation and education plans to meet the broader essential needs of a community.

Emphasis on meeting the mental health needs of particular target groups, such as children and the elderly.

Establishment of the CATCHMENT AREA principle which orients mental health care to the entire population within an entire geographical area.

Extensive involvement of the community and the consumer in the planning and operation of every CMHC.

One reason for the success of the community mental health centers that I have previously mentioned is the emphasis on responsiveness and accountability to the service area residents. Community mental health centers derive accountability to their catchment areas through community governance bodies, service area requirements, Federal monitoring, fiscal management procedures, and reviews of their programs by appropriate health planning organizations.

I shall now present a brief overview of the new law, with special emphasis upon the features that relate directly to the treatment of patients with diabetes. The new law provides CMHCs the resources and incentives to effect improvements in problem areas including range of services offered, quality of services, and provision of consultation and education services.

There is now a requirement for twelve essential services. These twelve services include the original five services plus seven new services. The original five services were out-patient, partial-hospitalization, emergency services, and consultation and education. The seven new services are services for the elderly, services for children, court screening before admission to State hospitals, follow-up care for patients leaving hospitals, transitional living programs in communities for former hospital patients, alcohol services, and drug abuse services. In addition, the legislation requires a great many assurances in order for the grantees to be eligible for Federal support.

In order to provide support for the old and new community mental health center programs, the new law establishes seven grant mechanisms. The grant mechanism which is most relevant to diabetes is for consultation and education grants to sustain the outreach and preventive programs that are difficult to finance.

It is also clear that Congress wanted the community mental health centers program to be responsive to local community residents. Thus, the emphasis upon local catchment area governing boards for each center as well as a State level advisory council. We think it is wise for the centers program to genuinely involve citizens as advocates for their own needs.

Because of this intent as well as the new consultation and education grant, it now becomes highly possible for CMHC staff to enter into consultation/liaison activities with diabetes clinics and with health professionals involved in the treatment of patients with diabetes.

Areas which such consultation/liaison work could address are many. The holistic view of the patient and the impact of illness on the person and his family (i.e. understanding how the sick view their world) are germane. Emotional problems specifically associated with diabetes (for example, reactive depression after initial diagnosis) can be addressed as well as the emotional issues associated with having a chronic incurable illness. The special problems of the juvenile diabetic are laden with the potential for psychological morbidity.

The task of helping the patient to accept the realities of his illness is an essential requirement to achieve the cooperation needed for adequate management. However, this must be accomplished without instilling unnecessary fears, hypochondriacal overconcern, and in a way which helps the patient avoid having his life rigidly governed by his disease. This raises the whole area of personality type as it relates to medical management. Examples include the aggressive person who may become hostile and resistive when he becomes ill, and the passive person who may become acquiescing and regressed.

Another CMHC mechanism (besides consultation) for addressing these and other issues is education. Information provided to the community at large and to diabetics and their families can help prevent some problems and allow for early intervention and treatment should problems occur. Training which alerts the primary care clinician to the influence of emotional factors in the patient's illness is helpful. This can lead to an understanding of when and how to deal with emotional issues as they become manifest in the patient and when to refer to the mental health specialist.

Funds from primary care agencies to include mental health input would stimulate such activities. Funds for research are needed--also needed are the manpower, facilities, and programs to implement and apply what is known.

Through consultation between a CMHC and a diabetes agency, the patients concerned would have access to more comprehensive health and mental health care.

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SUMMARY OF REMARKS BY JERRY M. WIENER, M.D.

Delivery of Services:

Diabetes, as much or even more so than any other chronic non-fatal illness, envelops the family with the child. There are numerous reasons for this reality, including the following:

1. The genetic factors which are involved realistically predispose the parents to feelings of guilt with consequent maneuvers of overprotection, inconsistency, excessive indulgence or overcontrol, resentment, blaming, depression, etc.
2. The disease affects diet, meal times, and activity patterns. It often requires direct but unusual involvement by the parent with the child's body (as in injections, attention to urination and urine) which influences the pattern and integration of developmental forces, e.g. dependency, sexuality, body image, privacy, autonomy.
3. The course of the disease and its management is more directly under the child's control whether by passive or active means, and the child may deny, avoid, or assert this control to either facilitating or destructive ends.
4. The chronic character of diabetes by itself means long-term stress influencing attitudes and relationships and involving long-term expense, all of which

impinge upon the flexibility which is required for adjustment to the normal developmental changes in a child moving from early childhood through adolescence.

The above points are considered to be only some illustrative highlights of the adaptive challenges facing the child and the family. Each individual adapts and copes uniquely and must be considered individually but also, and at the same time, in terms of both the reciprocal relationships within the family and the family as a unit.

Planning for Delivery of Services:

Ideally every managing physician, clinical nurse, and hospital clinic service would be both site and agent for the delivery of mental health services. Considering that the psychological and personality factors determine in large measure whether management will or will not be complicated and what the course of the disease will be, sensitive consideration of such issues at the outset makes the most, if not the only, sense. The major investment by mental health personnel should be at the level of primary care: informing, educating, and being available at the consultative level to primary care personnel.

At the level of primary and secondary care I suggest that consideration be given to the therapeutic value of both parent and child groups, as well as family groups, which would be directed by sophisticated, sensitive, and informed personnel. The personnel would not of necessity include high specialized psychiatric personnel, but such professionals might be combined with others less highly specialized.

I would also like to see opportunities for adjusted, older children or adolescents with diabetes to share experiences with younger individuals with diabetes, for example in mixed age groups.

In terms of tertiary care I would recommend the earlier utilization of specialized intervention than I now most often see. It would be preferrable to have an opportunity at intervention with highly specialized services before the problems have polarized and concretized. Could we develop, for example, some reasonably reliable and valid way for the prediction or early detection of those children and/or families who will progress into severe management difficulties?

Secondly, at the level of tertiary care, although it may seem obvious, it is worth noting that in order to be effective mental health personnel need experience with diabetic children and their families. I have been impressed by the calmness that physicians experienced with diabetes retain in the face of fluctuations in the status of their patients. This calmness, which is a reflection of maturity and experience, is a great asset in communicating security and avoiding manipulation, in other words providing a stable context for management.

The following are some other areas of importance and/or concern in the general area of diabetes and mental health:

1. I would have many reservations regarding assigning or looking to the Community Mental Health Centers for services particularly because of the cost of the program on a national scale and the extent to which they function by "non-medical" or "anti-medical" models.
2. There is a need for multiple therapeutic approaches--the group model is an important one.
3. Due consideration should be given to the importance of generic family responses (coping) to the diagnosis of a chronic or fatal illness: denial, guilt, anger, intellectualiztion, information seeking, depression (with detachment), often divorce as an outcome.
4. Research strategy should be approached from the standpoint of diabetes as a model for chronic illness rather than, or in addition to, diabetes as a unique issue.
5. In regard to the emotional health of the child with diabetes, we should keep in mind an earlier error regarding the schizophrenogenic child versus the schizophrenogenic mother or family.

SUMMARY OF WORKSHOP

During the course of the Workshop several important points were made which are worth high-lighting in a summary. First among these is the necessity for cooperation between health professionals in the mental health area and those who function in the other disciplines of medicine. If the total health needs of the person with diabetes are to be met, such interdisciplinary cooperation is essential.

The second most important emphasis in the workshop was that the health needs of people with diabetes can not be effectively and comprehensively met by a concentration of effort and resources in any one area. There must be a balance between the extreme importance of basic research into the cause, cure, and prevention of diabetes on the one hand and, on the other, a concern for the present quality of life of those who must now live with this disease. At the same time, while on-going treatment must, therefore, include consideration of the emotional factors involved, there is also a need for controlled scientific studies to further our knowledge of the psychological aspects of diabetes and to discover a means of early detection or prediction of those individuals and/or families who will progress into severe management difficulties.

On the delivery end, there is likewise a need for balance between an emphasis upon the Community Mental Health Centers, which are a significant resource and are of particular importance to the underserved portion of the population, and the resources of the total health delivery system beyond those centers.

In conclusion, the workshop stressed the importance of the psychological environment of the person with diabetes, that controlled scientific studies in this area of therapy can be accomplished, and that the delivery system for the treatment of emotional health must use a variety of both resources and modalities.

WORKSHOP
ON
DIABETES-RELATED PROGRAMS
OF THE
HEALTH RESOURCES ADMINISTRATION

April 30, 1976

Sponsored by the
National Institute of Arthritis, Metabolism,
and Digestive Diseases

WORKSHOP ON

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OF THE

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PRESENTATION ON THE
HEALTH RESOURCES ADMINISTRATION

by

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The Health Resources Administration (HRA) is concerned with the supply and quality of the health resources needed for our national effort to improve the delivery of health care services to all our people.

HRA is organized into two Bureaus and two Centers: (1) The Bureau of Health Manpower; (2) the Bureau of Health Planning and Resources Development; (3) the National Center for Health Services Research; and (4) the National Center for Health Statistics.

These organizations support health manpower training, facilities construction and improvement, statistical studies, health and vital statistics reporting, research studies on various problems of health care delivery and demonstrations of solutions to those problems, and health planning at regional State and sub-State levels.

The Office of the Administrator includes an Office of Health Resources Opportunity which is responsible for the assurance of equity of access for persons who for one reason or another are disadvantaged in seeking health care or careers.

The United States spent 7.7 percent of its Gross National Product on health in 1974. This, one of the highest rates in the world, amounted to more that $104 billion.

Americans visited their doctors more than one billion times in 1974. More than one out of every 10 of us went to the hospital at least once during the year. When in the hospital, the average stay was 10 days. Dentists found us in their waiting rooms 333 million times during the year. We lost 451 million days from work and another 222 million days from school.

Actually, about one half of the population made more than 94 percent of all reported physician visits, and a little less than half of the total population saw a dentist.

Half of America's 7,500 hospitals and seven out of every 10 hospital beds are located in Metropolitan areas, with average occupancy rates varying in Metropolitan general hospitals from 37.9 to 91.6 percent of capacity.

In 1972, the average daily cost to the more than 16,000 nursing homes which provided nursing care to their residents was $16.24. In 1973-74 it took the equivalent of 722,000 full time employees to staff these facilities.

In little more than a decade, between the fall of 1960-61 and June 1975, total student enrollment in medical and osteophathic schools rose by

77 percent -- from 32,000 to 56,700. Keeping pace, the Nation's supply of active physicians was about 343,000 in 1974, up from 251,900 in 1960.

In spite of this, 138 counties in 26 states, with a combined population of nearly a half million people, are without a practicing physician. Some poverty areas show ratios of one physician for every 10,000 residents.

HRA's manpower programs have attacked geographic maldistribution problems steadily over the past 4 years, particularly in the area of delivery of primary care. These programs include service-commitment student assistance programs, innovative approaches funded through special project grants and contracts, and Health Manpower Education Initiative Awards.

The Health Resources Administration was formed in 1973 to identify and help correct current and anticipated imbalances, inefficiencies, and deficiencies in the distribution, supply, use and cost of health care resources and services.

Some of the most serious deficiencies with which we are faced are:

- Access to primary care
- Rise in costs of care
- Unequal opportunities for health care and careers
- Inadequate methods of measuring and dealing with issues involving quality of care

Most of the Nation's personal health costs are being paid by third parties - Medicare, Medicaid, Blue Cross and Blue Shield - and some kind of National Health Insurance seems to be a possibility within a few years. Therefore, we must be concerned about other problems:

- Good services are not available everywhere
- There is a serious lag between the time knowledge is developed and the time it is put into practice
- Costly hospital care is often provided when home or outpatient care would be as effective
- Health and social services still do not work together smoothly
- Individuals need greater understanding of how to care for themselves and the purpose of health care services.

To meet these problems and issues, HRA is moving ahead with new resource and manpower planning. Resource planning is based upon a national network of new local Health Systems Agencies. These public and private non-profit organizations are required to develop a comprehensive plan to meet the health needs of all residents in their geographic areas.

The overall goal of health manpower development will be to help develop an adequate supply, mix, and distribution of health workers needed to operate the Nation's health care system. The strategy to reach that goal involves institutional support, student assistance, and special efforts to deal with primary care, productivity, and geographic distribution. HRA is also taking new initiatives in health services research and in statistical reporting and data utilization to give planners and others the information they need at every level from the community to the Federal so they can make informed decisions.

Our two main objectives are to improve the organization and structure of the health delivery system and to restrain the escalation of health care costs in this country.

As I said, we do this through:

- Health planning to avoid wasteful duplication and to improve resources allocation
- Research on increased health costs
- Data to gauge the Nation's health
- Data on costs of health care
- Cooperative systems of health data
- Develop primary care personnel
- Improve geographic and specialty distribution
- Promote the use of less expensive personnel to deliver health care.

Our tactical plan for conducting these activities is as follows: to improve our health policy making apparatus and process, we have to develop better ways to get timely and pertinent health data;

we have to develop a better research capability for health services research and more extensive analytical capability. We are currently developing national guidelines for health planning which should help our Health Systems Agencies approach their job in a better manner.

Our plan for attacking cost escalation is to improve the health care financial data and research to build a national resources allocation system through health planning to develop more efficient and economical health personnel to modify the utilization patterns and to implement a health prevention strategy. Finally, our tactical plan for developing essential resources is once again to develop a modern health data system so we know what resources we have and what are needed to have a policy oriented health services research system and to develop national and regional health manpower pools.

Our budget picture over the past few years is shown on the attached chart.

As you will see our manpower and other health resources activities are not categorical in nature but are general. This is the way it has been in the past,but I am not ruling out the possibility of both you and we developing some sort of model or demonstration program which concentrates on the use of personnel or health care systems for diabetes control. The other speakers from each of our Bureaus and Centers will tell you in more detail what their particular Bureau or Centers do.

BUDGET

	(In millions of dollars)			
	FY 1974	FY 1975	FY 1976	FY 1977
Manpower	550.4	484.5	428.9	319.0
Data	18.2	21.8	25.6	24.0
Research	52.9	35.9	26.0	24.0
Planning	116.5	90.2	90.0	90.0
Construction	303.3	138.0	84.8	--
Direct Operations	45.5	56.3	48.5	49.3
Total	1,086.8 1/	826.7 1/	703.8 1/	506.3 1/

1/ Excludes funds carried over from prior years.

THE NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND ITS POTENTIAL FOR IMPACT UPON PROBLEMS RELATED TO DIABETES MELLITUS

by

Dr. Gerald Rosenthal, Ph.D.

There are aspects of the National Center for Health Services Research (NCHSR) mission which inherently relate to the research and testing of innovative approaches to solving the problems associated with diabetes. Generally, biomedical research is not at the stage of developing a cure for the condition, and the major burden of helping to relieve the morbidity and suffering of diabetics in this country falls upon those who can deal with its effective management. The tools for such management are created through understanding patient behavior and coping mechanisms and creating patient services that will enhance the ability of the patient and the family to deal effectively with the condition. The National Center is concerned with the research and testing of such services and should, therefore, be looked upon as a resource in helping to improve patient care.

A look at the NCHSR portfolio of related research reveals projects which impinge on patient education and the quality of care delivered. Our memorandum of April 15 by Dr. Eleanor Smith to the Executive Secretary of DMCC describes projects which investigate such topics as new types of health care, manpower, the process of communicating health information, the physician/patient relationship, patient behavior, new approaches to screening, and streamlining laboratory processes.* These projects vary in their emphasis on diabetes as a target, but they all have implications for helping to solve problems associated with the disease. Also, recent years have shown an increase in staff contacts with behavioral and health services researchers who are interested in the design of research to investigate coping with diabetes and other chronic conditions, consumer self-help and self-care, new modes of health education, and group approaches to aid in management of chronic diseases.

The National Center is currently focusing its limited resources on eight health services issues:

1. Research on the quality of care
2. Research on inflation and health services productivity
3. Health care and the disadvantaged
4. Research on innovation in health manpower
5. Health insurance
6. Health services planning and regulation
7. Research on emergency medical services
8. Long term care research

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* See: DMCC 2d Annual Report, FY-1976.

This developing list contains items which include projects oriented toward diabetes problems and which can vary in diabetes emphasis at any given time, since the NCHSR mission does not approach research on a categorical disease basis. The list is not exhaustive in describing the National Center's activities and areas of research support. An example is our developing interest in consumer-oriented research such as the consumer self-care movement, the general field of health education and patient behavior, and the research aspects of the new Health Information and Health Promotion Act of 1976 (Public Law 94-317).

Much of the National Center's future contribution to diabetes and other chronic disease care will be through research and demonstration of consumer self-care and education. A draft report of the National Center's Conference on Consumer Self-Care in Health (March 1976) lists recommendations which are very consistent with diabetes services research needs: the survey of consumer knowledge and practices, the demonstration of interventions to promote behavior change, research and demonstration concerning the innovative use of manpower and the survey of current provider attitudes and behavior. The degree to which the National Center will support the recommendations will depend upon the availability of our resources, the saliency of the field of study in comparison to other research needs, and the quality of the research proposals that are developed.

For diabetes-oriented research which the National Center can support, the range of dependent variables for investigation is wide, e.g., changes in measures of the quality of life and levels of coping, changes in morbidity and mortality, and changes in the cost of care and the utilization patterns of health services. Valid research designs, reliable data, and the development of useful data collection techniques and instruments are only a few of the factors which can contribute to good research in this area.

Several possibilities exist to enhance the diabetes-oriented research and demonstration efforts supported by the National Center:

1. Consultation between the National Center and the National Commission leading to the development of contracts to promote specific research and demonstration projects.
2. The possible support of a national conference to plan or assess diabetes services research.
3. The development and circulation of an NCHSR solicitation for grant applications to do research on "Consumer/Provider Relationships." It might point to diabetes as an exemplary topic and cover the fields of (a) new health care manpower which interacts with the consumer, (b) the doctor/patient relationship, (c) consumer self-care in health, (d) survey research on consumer attitudes and health practices, and (e) consumer health education.

The National Center staff would welcome further discussion with the Commission regarding these ideas or any others to address the problem of diabetes mellitus.

DIABETES DATA IN THE NATIONAL CENTER FOR HEALTH STATISTICS

by

Robert A. Israel

The National Center for Health Statistics is exactly what the name suggests - the Federal agency responsible for producing, analyzing, and disseminating data on health in the United States. In the fulfillment of this mission, the Center designs and maintains national data collection systems, conducts research and training in statistical and survey methodology and cooperates with other agencies in the U. S. and in foreign countries in activities to increase the availability and usefulness of health data.

Through its surveys and inventories the Center produces national data on illness and disability and on the supply and use of health services. From our vital statistics program come the nation's official statistics on births, deaths, marriages, and divorces. In the Cooperative Health Statistics System we are building a coalition of federal, state and local agencies, working to produce data in sufficient geographic detail to serve state and local data needs.

At present the Center administers a dozen or so statistical systems which collect data on a regular periodic basis. I am going to describe only those which are our primary sources of information on diabetes.

One of these is the Health Interview Survey. This survey, the first to be established under the National Health Survey Act of 1956, is conducted throughout each year in some 40,000 households, selected as a national sample of the civilian, noninstitutionalized population. A relatively stable core of questions related to illness, disability, and health services utilization is asked annually. Each year, also, questions are asked about the prevalence of one group of chronic conditions - respiratory conditions one year, circulatory conditions another year, and so on - and about the effect of these conditions in terms of disability, doctor visits, and other measures. Such data on diabetes, as a condition of the metabolic system, were collected in the 1973 household interview survey and a report is in press.

In addition, diabetes is one of the "special" topics on the 1976 Health Interview Survey. This means that people who report having diabetes or that they are borderline or potential diabetics will be asked a supplemental set of questions - family history of the disease, and the type of treatment they are receiving, for example. We are also asking about certain conditions frequently associated with diabetes, such as vision problems. Like many of the special topics, the diabetes supplement was developed in cooperation with some of the prospective data users, in this case the National Commission on Diabetes, the American Diabetes Association, and the Juvenile Diabetes Foundation.

Our Health and Nutrition Examination Survey, another important source of data related to diabetes, provides data on nutrition status, health related measurements, prevalence of chronic disease and related health care needs, and on physical and intellectual growth and development patterns. These data are obtained through successive programs of physical examinations, tests, and measurements of national population samples of specified ages conducted by NCHS field teams. Diabetes was first studied in the examination survey of adults in the early 1960's As you may know, it showed, on the basis of blood glucose levels after challenge, that the number of persons with what is generally considered evidence of "unknown" diabetes was substantially greater than the number with known diabetes. The current HANES, which began early this year, will again be obtaining estimates of the prevalence of diabetes.

A third source is the mortality data from the national vital statistics. These data are based on the information on cause of death reported on the death certificates filed in the states and are produced annually. The mortality data are a rich store of information on differentials in death rates from diabetes among various sub-groups of the population. Unlike the data from the two surveys described, for which we can now produce only national and regional estimates, the mortality data are available for small geographic areas. Analysis of trends over time as well as comparison of our rates of deaths from diabetes with the rates of other countries is possible.

There are two other surveys in which diabetes is one of the diagnostic conditions for which data are obtained. One of these is the relatively new National Ambulatory Medical Care Survey, a statistical study of visits to office-based physicians. The first continuing national survey in the ambulatory care area, it is producing information on the reasons people visit the doctor, the doctor's diagnosis, the treatment prescribed, and the disposition of the case. The second survey is the Hospital Discharge Survey, based upon a sample of discharge records of a national sample of short-stay hospitals.

As these specific surveys indicate, the National Center for Health Statistics draws information from various sources: the people themselves, the providers of care, such as hospitals, nursing homes, and physicians, and from records of care and of vital events. The data derived are available, in turn, to all of them and to any other prospective users. Our primary form of release is formal statistical reports. In addition, aggregate data tapes may be purchased and special tabulations can be prepared in answer to specific requests. The only restrictions placed on the release of data are those which relate to confidentiality. We will be glad to receive your requests for vital and health statistics.

PUBLIC LAW 93-641

THE NATIONAL HEALTH PLANNING AND RESOURCES DEVELOPMENT ACT

by

Colin C. Rorrie, Jr., Ph. D.

I. INTRODUCTION

It is indeed a pleasure to be here today to discuss Public Law 93-641. What I would like to do is briefly give an update on the status of the implementation of the Act, then give a brief discussion on some of the key factors which I feel will determine whether P. L. 93-641 will be any better than prior planning programs.

II. UPDATE

A. Area Designation

On September 2, 1975, 202 health service areas were designated. This was the first step necessary in order to designate and fund the new regional health systems agencies that are to take the place of the areawide comprehensive health planning agencies.

B. Health Systems Agency Designation

On October 17, 1975, a Notice of Proposed Rulemaking was published in the *Federal Register*. Over 900 comments were received and final regulations were published on March 26, 1976. On the basis of these final regulations, 100 health systems agencies were designated on April 9. We expect to designate another group of agencies around June 14; with the remainder to be approved toward the end of August.

C. State Health Planning and Development Agencies, Certificate of Need, Revision to Section 1122

The proposed rules covering this area were published on March 19, with a 45-day comment period which ends on May 3. If enough states are interested, we will begin funding the new state agencies by June 30 by using the proposed rules. In any case, most of the new state agencies will be in place by October 1, when the Federal Government shifts to a new fiscal year. Since we expect to receive a substantial number of comments on the certificate of need rules, we do not expect to publish final regulations until late in the fall.

D. Other Regulations

There are a number of other regulations covering such issues as review and approval of Federal programs, review of appropriateness of existing institutional health services, area health services development fund, health systems plan, annual implementation plan, state health plan, state medical facilities plan, and the construction program itself (Title XVI) which will be published in the fall. It should also be mentioned that we do not expect to make any construction funds available under Title XVI until sometime in 1977. This is because of the legislative requirement that the health systems agencies be in place, along with the state agency and the required health systems plan, annual implementation plan, state health plan, and state medical facilities plan having been completed

III. Reality Factors

A. Level of Participation Within Community

Will the major participants within the community who should be involved and who will be affected by the planning process be a partner in P.L. 93-641? This includes not only providers and consumers, but local government and payors.

B. Quality of Plans

Since a major focus is on planning, the quality of what develops will largely revolve around the level of participation and the demands and inputs they put into the planning process.

C. Financing

The problem in the last planning programs was inadequate funding. Currently most health systems agencies will get $.20 per capita, which is a decrease for a number of agencies over what they have been obtaining. Yet the functions to be performed have been expanded. This level of funding will directly impact on the numbers of staff and their quality in terms of professional preparation and experience.

D. Staff

A key to this effort will be the type of staff. Prior programs were plagued by inadequate staff and lack of relevant training and experience. That potential again is quite probable, in spite of specific requirements within the Law regarding the number of professional staff and their skills, if the funding level does not increase.

E. Role of the Federal Government

Simply stated, will the Federal Government be of assistance to the agencies or will it play its usual and customary role of being an albatross around the neck of the planning agencies?

TRAINING THE NATION'S HEALTH MANPOWER

by

David A. Kindig, M.D., Ph.D.

Assuring that the Nation has an adequate supply of trained manpower to staff the health care system is the primary concern of the Bureau of Health Manpower. The Bureau, a part of the Health Resources Administration, supports the training of various kinds of skilled health manpower and not any categorical type. Its programs focus on the production, use, and distribution of health personnel as an approach to addressing the problems of access, cost, and quality of care. Particular attention is being given to alleviating inequities in the distribution of physicians by location and specialty.

Federal support of health professions training dates back to 1963 when the Health Professions Education Assistance Act was enacted out of concern over a shortage of skilled health workers. Legislation also has been enacted to support related types of health manpower. Currently, the Bureau supports the training of physicians, osteopaths, dentists, optometrists, pharmacists, podiatrists, veterinarians, nurses, allied health, and public health workers.

A major source of Federal support for health professions and nursing education has been capitation grants--awards made on the basis of enrollment. Capitation is awarded to encourage schools to maintain enrollment levels and improve curricula. In Fiscal 1975 health professions schools were awarded $150 million in capitation grants and nursing programs were awarded $34 million.

Institutional support also is provided by special project grants which may be awarded to health professions and nursing schools for various activities seeking to improve the curriculum and to encourage students to practice in areas and specialties in greatest demand. In Fiscal 1975 special project awards to health professions schools amounted to $38 million and to nursing schools $15 million.

The training of various auxiliaries is being supported in an effort to increase the output of medical and dental services. The Bureau is funding programs to train physician assistants, nurse practitioners, and expanded function dental auxiliaries, as well as programs to educate health professionals in the use of auxiliaries.

Programs concerned with the use and efficiency of health manpower also supported under the Health Manpower Education Initiative Award Authority. HMEIA awards have been made to support interdisciplinary team training, health manpower educational development, and studies of the roles and functions of physican assistants.

The Bureau's 11 Area Health Education Centers (AHECs) are supported under HMEIA authorities. AHECs are demonstrating methods of conducting decentralized programs of health professions, nursing, and allied health education. About 15,000 students in these fields are expected to take some part of their clinical training in shortage area settings through the Area Health Education Centers.

More than $110 million, a record part of the Bureau's 1975 appropriation of more than $600 million, was devoted to student assistance, particularly programs requiring students to practice in underserved areas. Some 1,500 Public Health Service Scholarships were awarded to medical students in return for service in shortage areas. The bulk of student assistance funds were awarded under such programs as health professions and nursing loans and scholarships, public health traineeships, and allied health traineeships.

Through the Office of the Director and the four operating Divisions, the Bureau of Health Manpower works to improve the training and increase the supply of health workers. All four divisions--Medicine, Dentistry, Nursing, and Associated Health Professions-- carry out planning, coordination, evaluation, and support activities in their respective parts of the manpower field.

The Division of Medicine provides the expertise and leadership necessary for education programs for the development, use, and credentialing of such personnel. In Fiscal 1974, the Division supported 138 family practice programs with some 2,000 residents in training. The Division also has awarded contracts to medical schools to develop and conduct model primary care residency programs.

The Division of Dentistry supports training, recruitment, use, and credentialing programs in dental manpower. In Fiscal 1975, the Division awarded $5.5 million to 28 TEAM--Training in Expanded Auxiliary Management--programs. This permitted almost 1,500 students to receive training in working with auxiliaries trained in expanded dental functions.

The Division of Nursing supports and conducts programs in all areas of nursing problems, aids States and local areas in upgrading their nurse training programs, and is engaged in high priority programs to expand the roles of nurses, broaden the socio-economic base for nurse recruitment, and increase health resources for underserved areas. In Fiscal Year 1975, some $37 million was approved for construction of nurse training facilities. Capitation grants were awarded to 981 nursing programs with a total enrollment of more than 180,000 in the 1973-74 school year.

The Division of Associated Health Professions is concerned with optometry, podiatry, pharmacy, veterinary medicine, public health, and the allied health professions. A major focus is on the improvement of effectiveness and efficiency of allied health professions education opportunities. The Division also provides eligible schools of public health with formula grants and offers project grants for graduate public health training and traineeship. In the past 2 years, nearly 11,000 returning veterans found jobs or training under the MEDIHC--Military Experience Directed Into Health Careers--program, a State-oriented counseling and referral program of the Division.

Legislative authorities for virtually all health manpower training authorities expired on June 30, 1974. Nursing authorities were renewed on July 29, 1975 when Congress enacted the Nurse Training Act of 1975. Health professions, allied health, and public health programs are being conducted for the second straight year in Fiscal 1975 under a continuing resolution while Congress is attempting to draft new health professions education legislation.

WORKSHOP

ON

DIABETES-RELATED PROGRAMS

OF THE

HEALTH SERVICES ADMINISTRATION

July 6, 1976

Sponsored by the

National Commission on Diabetes

WORKSHOP ON DIABETES-RELATED PROGRAMS OF THE HEALTH SERVICES ADMINISTRATION

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PRESENTATION TO THE NATIONAL COMMISSION ON DIABETES

by

Louis M. Hellman, M.D.
Administrator, Health Services Administration

It is an honor for me to be addressing the distinguished members of the National Commission on Diabetes. I and several principal staff members of the Health Services Administration have read with great interest, and some degree of awe, Volume 1 of your report to the Congress of the United States.

We commend the Commission for a job well done and believe the report will prove to be a vehicle for some giant steps forward in this Nation's progress towards better health. We also believe, however, that the Commission's report may be less than perfect in that it largely ignores the major health care delivery agency in the Public Health Service and the special populations we serve, that is, those who have limited, if any, access to the health care system.

In our presentation to you today, we plan to discuss briefly what the Health Services Administration does, what it does in relationship to diabetes, including what it has done or can do to implement the recommendations of the Commission, and what help it may require from the Commission in order to further improve the delivery of services to diabetics.

I have invited knowledgeable HSA officials to attend this meeting so that they will be available, following my presentation, to respond to any of your questions, to amplify information at your request, and to participate, if you so desire, in a frank and open discussion of various issues related to the delivery of health services. I believe a candid discussion of this nature will be revealing and pertinent to your interests as well as ours.

As some of you may know, the programs of the Health Services Administration are structured around five basic missions. Those five missions are:

1. To place health personnel and services in underserved areas or, as we say, to build primary health care capacity in underserved areas;
2. To maintain the established primary health care capacity, especially in those situations where it cannot be self-sustaining;
3. To improve the organization and efficiency of health care delivery;
4. To promote effective and equitable public and preventive health services; and
5. To assure the quality of federally financed health services.

In order to carry out these missions, HSA performs in the following specific ways:

* Direct health delivery programs, such as those administered by the Indian Health Service and the Bureau of Medical Services;
* Project grant supported health service programs, which include Community Health Centers, Migrant Health programs, and Family Planning programs.
* Formula grant health programs, such as grants to States for Maternal and Child Health Programs.
* Programs for methods of organizing and delivering health services, such as Health Maintenance Organizations,

Emergency Medical Services, and the National Health Service Corps.

- And programs for assuring quality of health care, such as Professional Standards Review Organizations.

I realize this may be a lot to digest at one time, but copies of this presentation will be available to each of you to review at your leisure. At that time, I hope that what may appear, at first glance, to be a jumble of programs and program activities will be seen as a cohesive structure.

That structure consists of four major organizations. These major HSA components are the Bureau of Community Health Services, the Bureau of Medical Services, the Bureau of Quality Assurance, and the Indian Health Service.

The Health Services Administration has a staff of 17,000 people and a 1976 appropriation of $1.3 billion. Of the 17,000 positions, 1,400 people work in HSA headquarters, 600 are employed in the HEW Regional Offices, and 15,000 employees, the bulk of our staff, work in the field, which includes the Indian Health Services facilities and the Public Health Service hospitals and clinics.

Each of HSA's three Bureaus and its Indian Health Service conducts some activities relevant to diabetes mellitus. However, at this point in time, HSA's interest in diabetes relates primarily to the fact that this is a disease that affects, to varying degrees, the populations served by our programs, particularly the American Indians.

The Indian Health Service is the primary health provider for 538,000 American Indians and Alaskan natives. It provides direct health services, including health education, to Indians, Eskimos and Aleuts in 51 hospitals, 99 health centers, and several hundred health stations.

Among the comprehensive health services provided the Indian and Alaskan Native people, and which are among the major activities of Indian Health Service workers, is the diagnosis and treatment of diabetes mellitus and associated conditions.

Diabetes mellitus is much more prevalent in most American Indian tribes than it is among non-Indians. Some tribes, such as the Pima and Papago, have diabetic rates 10 to 15 times the presumed frequency among whites. Although there is no way of determining from data currently available the exact number of cases of diabetes in the Indian Health Service population, the best estimate of the number of persons with diabetes mellitus, both diagnosed and undiagnosed, would be approximately 20,000, or about 40 per 1,000.

Of the three recommendations made to the Health Services Administration by the National Commission on Diabetes, one specific recommendation was addressed to the Indian Health Service. In that specific recommendation, the Commission suggests that the Indian Health Service continue its cooperative efforts with NIH to study the epidemiology of diabetes in selected Indian populations and that IHS should review its overall health care programs to ensure that they adequately address the specific needs of Indians with diabetes.

These objectives the Indian Health Service certainly intends to carry out, and in the event additional resources are made available in diabetes control programs, they can be effectively utilized within the Indian Health Service.

HSA and its Bureau of Medical Services, another direct provider of services, were concerned that the National Commission on Diabetes did not include the Public Health Service hospitals and clinics in its specific recommendations for the utilization and organization of national health resources to combat diabetes. The nine hospitals, including the Hansens Disease Hospital in Carville, Louisiana, and 26 outpatient clinics in the system constitute a nationwide network within the Department of Health, Education, and Welfare for research and delivery of health services specifically related to diabetes mellitus.

These hospitals and clinics have the capacity to participate in the full spectrum of prevention, including health promotion, patient and provider education, early diagnosis and treatment, limitation of disabilities and rehabilitation, as well as research capacity.

A continuous increase in patient load at the PHS hospitals and clinics brought the number of inpatient admissions in F.Y. 1975 to 30,956, up from the previous year's total of 27,874. Outpatient visits, including hospital outpatient, free standing clinics, and contract physician visits, totaled 1,644,000 as compared with 1,534,000 in fiscal 1974. The average daily patient load amounted to 1,357, an increase of 6.6 percent over the previous year.

I think the resources of the PHS hospitals and clinics should be of particular interest to the Commission because of the present and potential capability of the hospitals and clinics to deliver services, develop programs to demonstrate the feasibility of new concepts or techniques and the ability to conduct a wide range of research activities in several categories, including neurological, dietary, dental, prostheses for insensitive limbs, as well as that category of research included in the general area of health services research. Several of the facilities have the capacity to undertake research useful to combat diabetes, and more than one are delivering diabetes control services right now. The PHS hospitals and clinics now have statutory authority to share needed facilities with the non-beneficiary community. Therefore, they offer an unusual centrally coordinated Federal resource for provider services and health service research.

The Health Services Administration is interested in expanding diabetes-related activities in our hospitals and clinics and would welcome the opportunity to cooperate with the Commission in this regard. We recommend, therefore, that the National Commission consider the resources of the Public Health Service's facilities in its specific recommendations for the utilization and organization of national health resources to combat diabetes, and that in its specific recommendations to Federal agencies, the National Commission on Diabetes should encourage the consideration of funding programs in PHS hospitals and clinics as part of the Federal intramural funding activity.

In addition, HSA recommends that the Commission consider the inclusion of other Bureau of Medical Services resources in your deliberations regarding the coordination of public and private sector efforts to improve the care of persons with diabetes, as well as others at high risk. For, also contained in the Bureau of Medical Services are the Division of Federal Employee Health, the Division of Emergency Medical Services, the Division of U. S. Coast Guard Medical Services, the Division of Health Maintenance Organizations, and the medical programs of the Bureau of Prisons and the Office of Federal Employee Compensation. Some of these programs provide extensive opportunities for health education with reference to diabetes and also lend themselves to diabetes screening.

In fact, during Fiscal Year 1976, approximately 40,000 Federal employees in Division of Federal Employee Health units will have participated voluntarily in the Division's diabetes screening program. Positive screenees are referred to their private physicians for definitive diagnosis and follow-up treatment.

Another of HSA's bureaus, the Bureau of Quality Assurance, has two component organizations directing efforts to assure that the quality of Medicaid, Medicare, and other Federal programs' services meet nationally accepted standards; and it also has an End-Stage Renal Disease program.

The End-Stage Renal Disease program develops, interprets, and evaluates health care and health-related policies for implementation of the end-stage renal disease provision of the Social Security Act and coordinates implementation of these policies with Medicare.

The other two programs under the jurisdiction of the Bureau of Quality Assurance are the Professional Standards Review Organizations and the Medical Care Standards Program. The Medical Care Standards program develops, with the Social Security Administration and the Social and Rehabilitation Service, conditions and standards of participation for providers of health care services under the Medicare and Medicaid programs. The Professional Standards

Review Organizations program, as you know, involves a nationwide network of nonprofit organizations of physicians to assure the necessity, appropriateness,and quality of federally financed health care services.

An integral part of the PSRO hospital review system are Medical Care Evaluation Studies. Each PSRO is required to perform a specified number of such evaluation studies in each hospital in its area. Most of these studies are performed at the hospital level. The PSRO or the hospital selects topics to investigate which represent known or suspected health care problems in the local area.

Three essential components of any Medical Care Evaluation Study are:

1. The development of criteria against which aspects of the care and services are compared;
2. The development and implementation of education or other change program designed to correct the deficiencies uncovered; and
3. A follow-up study to determine if the deficiencies were corrected.

The Bureau of Quality Assurance provides technical assistance to the PSROs in fulfilling their review obligations. This technical assistance, as related to Medical Care Evaluation Studies, could include suggested topics for studies, model protocols, sample criteria, and help in organizing multihospital or areawide studies.

Although the Bureau is not authorized to require a nationwide Medical Care Evaluation Study on a particular topic, with adequate support emanating possibly from a recommendation by the National Commission, the Bureau could assist the Commission in developing model protocols for conducting Medical Care Evaluation Studies on diabetes and assist in coordinating several PSROs to perform such studies, conduct the educational programs that would be necessary, and assure follow-up.

Now let us turn to HSA's fourth major organization, the Bureau of Community Health Services. This Bureau administers a broad range of programs designed to reach people who are underserved, or unserved, by the Nation's health services systems.

The projects and programs of the Bureau of Community Health Services provide primary health services, including preventive and curative services, to their target populations. In addition, many of the programs provide secondary and tertiary care to selected groups. The spectrum of services from outreach through screening, diagnosis, treatment, follow-up counseling,and education may be provided.

Although diabetes mellitus is not singled out for emphasis, it is safe to assume that many thousands of diabetics are being seen in these programs.

It has been estimated that in F.Y. 1976 a total of 2,091,000 people received comprehensive health services in Bureau-supported Primary Health Care Centers. In addition, 400,000 migrant and seasonal farmworkers and their families received health services through 105 Migrant Health Projects and 3.8 million women and men received comprehensive family planning services, including health screening and genetic counseling,through 226 Family Planning projects.

Also in F.Y. 1976, the National Health Service Corps provided health services to 670,000 people in critical shortage areas and nearly 16 million people received Bureau-funded maternal and child health services.

It is needless to say that many of the Bureau of Community Health Services' projects can be used in partnership with NIH developed research protocols. But this, of course, would necessitate increased properly-trained staff support and additional resources.

The trend in the Bureau of Community Health Services, as in all HSA programs, has been to move away from episodic care to continuous comprehensive care. Of course,this does not imply that patients with particular diseases are neglected or that categorical disease initiatives can not be used as a means to bring the patient to comprehensive health services. What it means is that the very nature of the Bureau's programs tend to avoid concentration of resources on particular diseases.

Some key staff feel that the most useful service efforts may be in public education, particularly in the field of nutrition, and in medical care for the treatable consequences of diabetes. Increased efforts in these areas are already underway, but please bear in mind that, with limited resources crying out for priority use, the treatment for some other diseases, such as hypertension, are more likely to have a greater effect upon the morbidity and mortality levels of the specific target populations of the Bureau of Community Health Services.

And now, before concluding my presentation and before making some other principal HSA officials available to the National Commission on Diabetes, I simply ask why the Commission recommended that responsibility for the Diabetes Control Program be delegated to the Center for Disease Control along with staff positions and funds? Should not diabetes prevention, disability limitation, and treatment, which are mostly personal health services, be logically housed in HEW's principal health services delivery agency, the Health Services

Administration?

And now, Commission members, my staff is at your disposal. Good luck to us all in our combined battle against diabetes and in our struggle for better health.

SUPPLEMENTAL PRESENTATIONS AND SUGGESTED PRIORITIES FOR DIABETES-RELATED PROGRAMS

Indian Health Service:

Dr. Swetter spoke of the unique research potential that exists through the Indian Health Service noting that IHS is the primary source of health services to the Indian population, thereby concentrating the health data, and that the populations served are far less mobile than the general population, thereby making them an excellent control group for research purposes. He also noted that many health related problems exist in the IHS-served populations which could readily be the basis for research projects, including projects involving diabetes. Whereas the Pima Indians have been extensively studied, other population groups have been neglected. Such potential research areas would not be duplicative of the Pima Indian studies.

Dr. Swetter presented priorities for additional programs needed by the Indian Health Service, as follows:

1. Expansion of present manpower, training sites, and the training of existing personnel;
2. Expanded research activity to include other IHS areas;
3. The right of Indian communities to contract directly for diabetes control programs;
4. Setting up five model diabetes control programs.

Dr. Rimple discussed the programs of the Bureau of Medical Services (BMS) in general and presented a summary of the activities of the Divisions of Federal Employee Health (FEH), Emergency Medical Services (EMS), and Health Maintenance Organizations (HMO) with respect to areas of the Commission's concerns. In EMS, basic life support capability for handling all kinds of emergencies, including diabetic emergencies, was an important goal. In Federal Employee Health, diabetic screening was now routinely performed in health units.

The HMO program provides funds through grants, contracts, and direct loans to assist organizations in developing and operating comprehensive, alternative, and cost effective health care delivery systems. This program also lends itself to the establishment of educational and related activities for the diabetic. Dr. Rimple offered to arrange appropriate meetings with BMS program directors to explore specific areas of cooperation.

Dr. Hinman expressed three needs of the Division of Hospitals and Clinics. These were:

1. Audit instruments which give minimal and ideal criteria sets for medical care standards for treatment and management of diabetes, particularly in the ambulatory area;

2. Patient education protocols around specific educational objectives;
3. Provider education protocols.

Bureau of Quality Assurance:

Mr. Kelly stated that criteria sets for diabetes were also needed by the Bureau of Quality Assurance (BQA). At the present time, BQA is testing a Medical Care Evaluation (MCE) study for hypertension and a similar study could be developed for diabetes. The commission should encourage NIAMDD and BQA to work together.

It was noted that BQA is relatively new and is currently involved in setting up procedures to determine standards. Each Professional Standards Review Organization (PSRO) will develop standards. A model set of criteria regarding diabetes would be helpful to the individual PSRO's.

Bureau of Community Health Service:

Dr. East, Bureau of Community Health Services (BCHS), explained that BCHS's mission was to implement care for the underserved. At the present time, the data system in use does not allow for collection of disease-specific information. In the next 14-16 months an internal medical audit will be developed by each project. Regional workshops to help obtain minimum criteria sets for certain diseases will be held, but BCHS needs to know that such protocols would be widely accepted. However, regarding diabetes, agreement does not appear to be near at hand.

In terms of research potential it was noted that some of the geographical areas which are served by BCHS have more stable populations than those of the nation in general. This could be helpful in providing a research base.

SUMMARY OF DISCUSSION

Dr. Hellman's presentation concluded with the question as to why the Commission recommended that responsibility for diabetes control programs be delegated to the Center for Disease Control (CDC) along with recommendations for staff positions and appropriations. Dr. Crofford responded that it was not intended that the mechanism set up with CDC be exclusive; rather, that this is an enormous problem and the Commission proposed one specific way of dealing with the problem. He continued that in nine months the Commission was unable to totally come to grips with the problem. In addition, the HSA did not submit a plan to the Commission as did CDC. There was, however, no intention to close the door, but it had been difficult to identify HSA programs relating to diabetes. He further stated the Commission was in a holding pattern while they identified mechanisms by which HSA can be involved. This is not the end, and there will be a continuance of effort to involve other agencies in diabetes-related activities either by the Commission or by the National Diabetes Advisory Board when that body is established.

In response to a question, Dr. Hellman clarified HSA's present scope of activity, in contrast to some years ago, as directed toward comprehensive health care, including prevention and screening, rather than a categorical approach to health care delivery.

Dr. Cahill asked Dr. Hellman if HSA were given an additional $50 to $100 million to improve the care of diabetics, what would HSA do with that money?

Dr. Hellman responded that a more realistic question should be, if he were required to cut back by that amount, where would he make changes? But,if he did have additional funds, his priorities would probably be to first give a fair amount to the Indian Health Service. Next, funds should be allotted to the Bureau of Community Health Services which has comprehensive health programs covering the whole spectrum of the poor. Over 15 million individuals receive their health care in these programs, and the Commission Report documented that these population groups have particular needs. Health Maintenance Organizations (HMO's) would also have a high priority. When the current funding phrase is completed there will be over 100 HMO demonstration programs.

Mr. Popkin added that many programs supported by the Community Health Service have the capacity to provide manpower for follow-up education and continued treatment. In addition, most state nutritionists are paid through Federal Maternal and Child Health funds.

Dr. Hutchins said that the definition of "crippled" children is determined by the states, but that the number of children with diabetes is not high when compared with other diagnoses.

Dr. Boshell raised the issue of the very high costs for comprehensive health services and asked, what would be the smallest amount of additional money to HSA that could be expected to make an impact on diabetes? In response to this question it was asked whether the Commission and HSA could work cooperatively to develop a program relating to diabetes? Dr. Hellman replied that this could be worked out, and that this approach could lead to specific program recommendations, including budget estimates. Dr. Cahill commented that it was not the National Commission's intent to extend the present level of care but rather to set up model systems to develop the best care and to develop methods of evaluation. Concern was expressed that if the same amount of funds are spread thinner, the results will be worse. Dr. Hellman responded that care must be taken to avoid programs which could become a "bottomless pit" waste of money and which do not deal with the basic problems. The Indian population offers both unique problems and a unique population base, and it could be studied more closely. Also the Federal Employee Health constituency offers a fairly controlled population.

Mr. Popkin stated that since each categorical disease entity tends to develop its own system instead of combining with existing systems and programs, he would urge that the present HSA-supported neighborhood Health Centers and Maternal Child Health

Centers be utilized and incorporated into the proposed diabetes centers.

Mrs. Whittlesey emphasized that the involved agencies should be initiating this kind of coordination.

Dr. Haddock discussed the importance of manpower relating to these considerations.

Dr. Hinman noted that the main purpose of the Public Health Service hospitals was to provide care. Training programs are on a non-categorical basis. They do provide limited fellowships in cardiology, but none in diabetes. These hospitals would enthusiastically accept agreed-upon criteria sets in professional audit, education, and treatment.

Dr. Leffingwell commented that the Division of Federal Employee Health has extensive data relating to diabetes, but resources need to be identified to utilize such date for research purposes.

Mrs. Graber reported on two meetings she had recently attended where the Indian population had expressed their needs. In the first conference their priorities were: human and communication needs, such as transportation, hearing aids, dentures, eye glasses; diabetes and arthritis clinics; and development and use of Indian norms not non-Indian ones for health appraisals. In the second conference (for women), nutritional needs ranked first.

In regard to the Indian Health Service, it was emphasized that a high priority of the Indian population is the right of Indian communities to contract directly for control programs, such as diabetes control programs. It was suggested that the Indian Health Service should explore this with the Center for Disease Control, and Dr. Flynt responded that he could foresee no problem in principle and was sure that CDC would be cooperative in discussing the matter.

It was also suggested that CDC could possibly work cooperatively with BCHS to obtain data. Dr. East commented that BCHS does not have the expertise to design proper research protocols, etc., but it could cooperate in the implementation of a research study.

It was suggested that HSA and ADAMHA be encouraged to work cooperatively in the area of emotional/psychological support for people with diabetes and their families. Mr. Popkin responded that Indian Health Service and the neighborhood health centers provide some degree of emotional/psychological support. It was stressed that emotional care must be included in basic criteria sets, even for minimal criteria.

The Commission thanked the representatives of HSA for their presence, the informative discussion, and their concern for a cooperative effort.

APPENDIX

HSA Organizational Charts

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Health Services Administration

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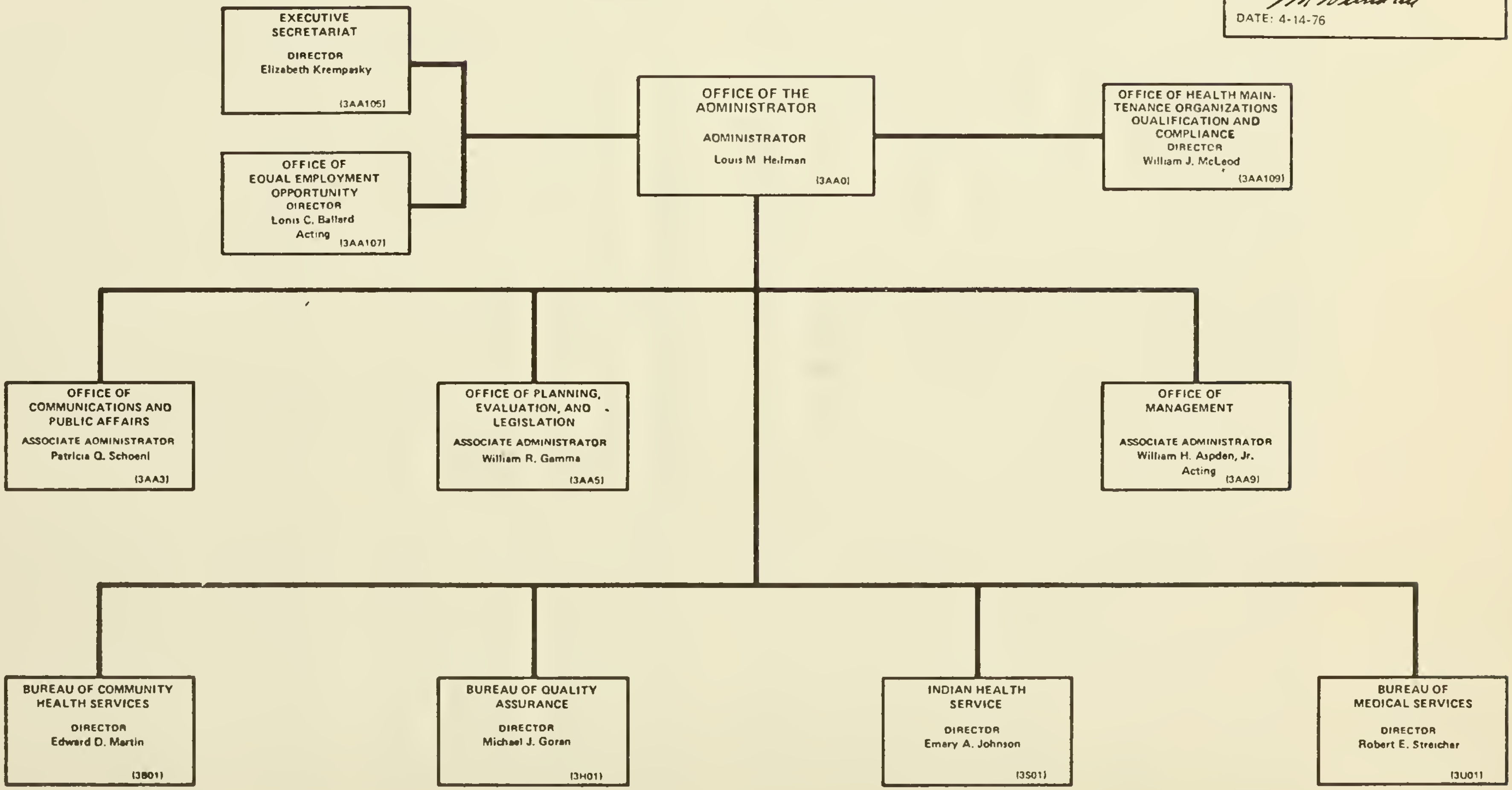
DATE: 4-14-76



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

Health Services Administration

BUREAU OF COMMUNITY HEALTH SERVICES

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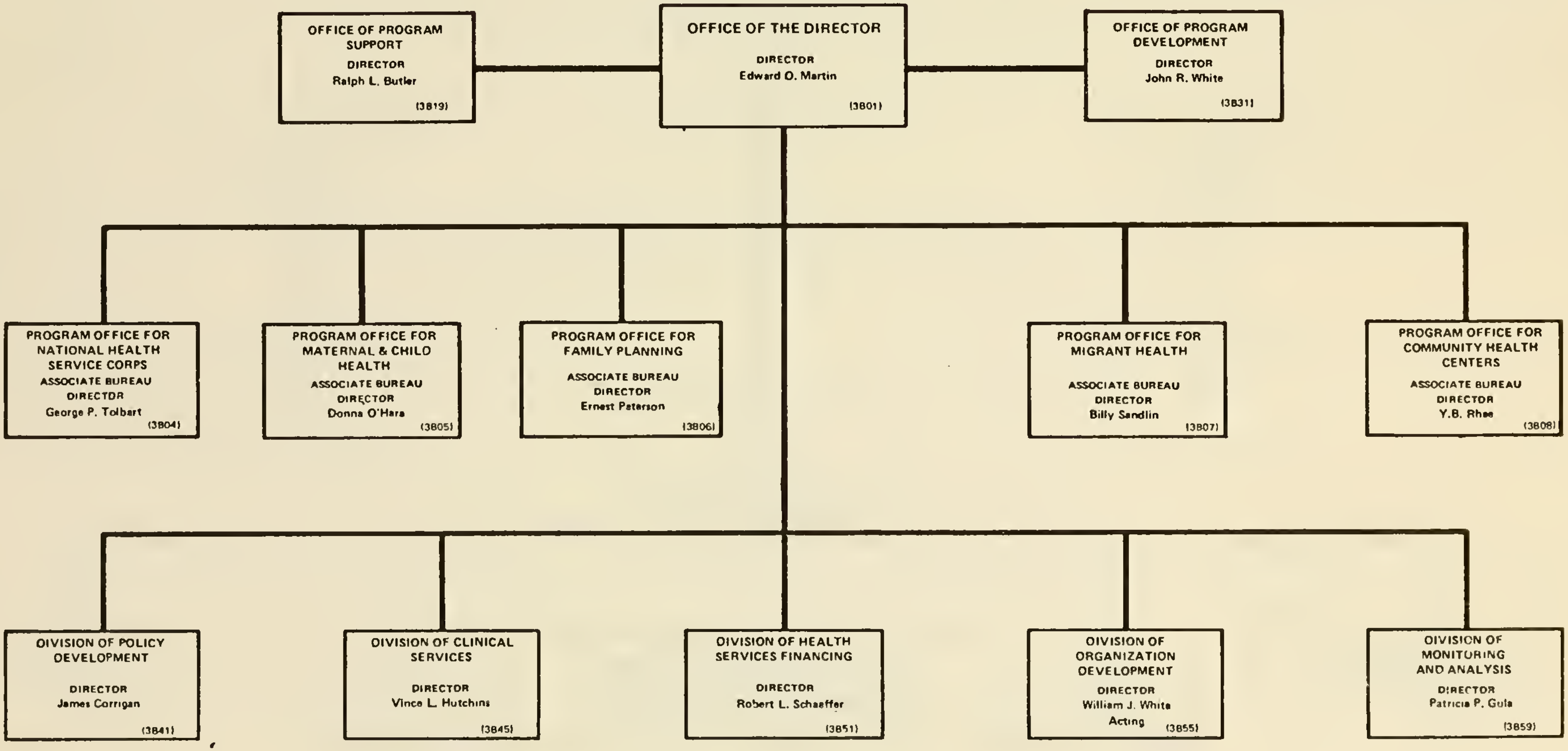
APPROVED: Edward D. Martin
DATE: 4-14-76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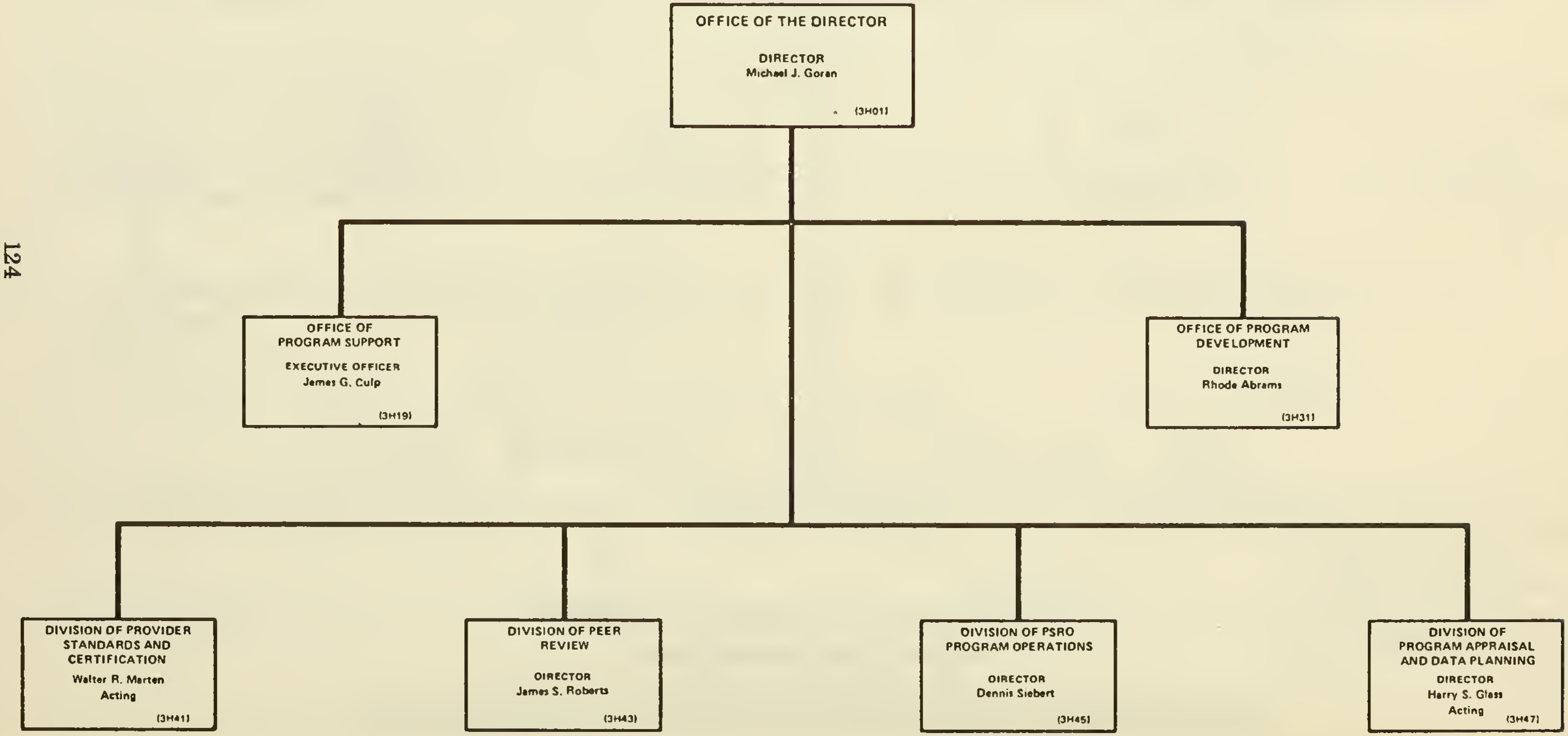

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BUREAU OF MEDICAL SERVICES

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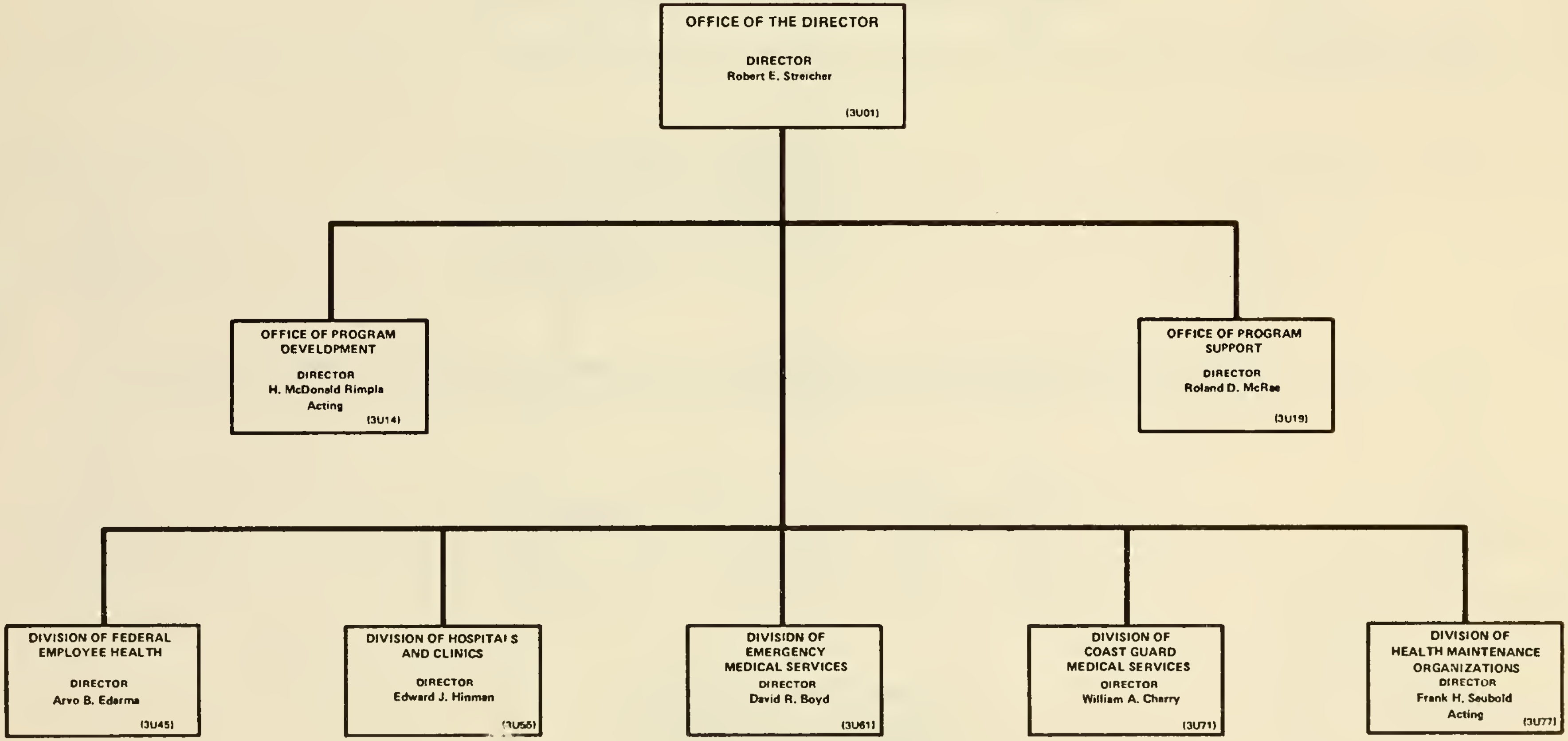

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Health Services Administration
INDIAN HEALTH SERVICE

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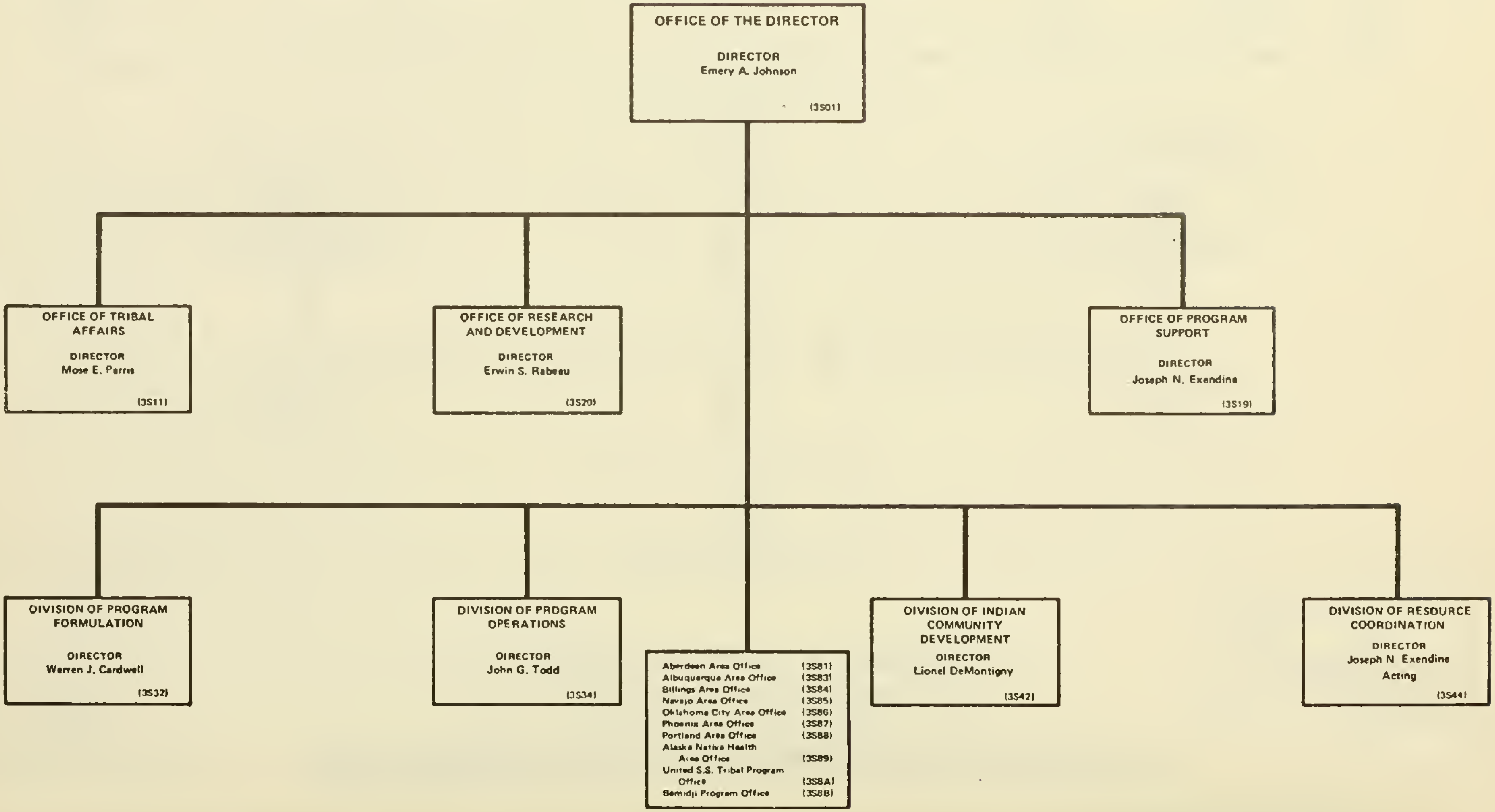
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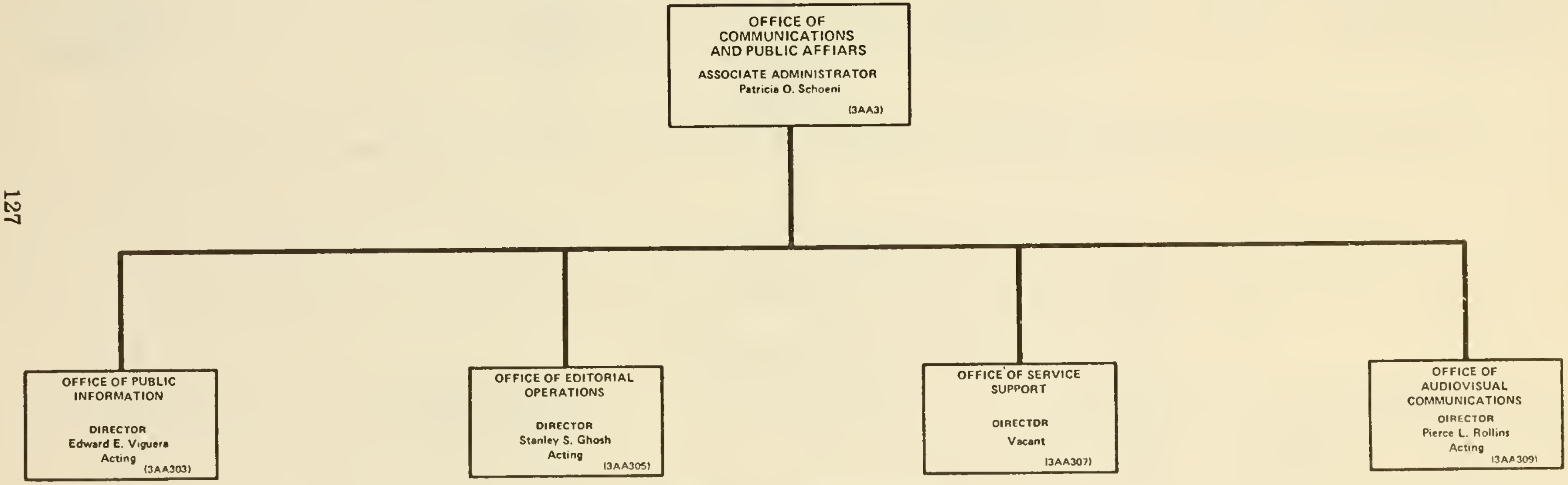

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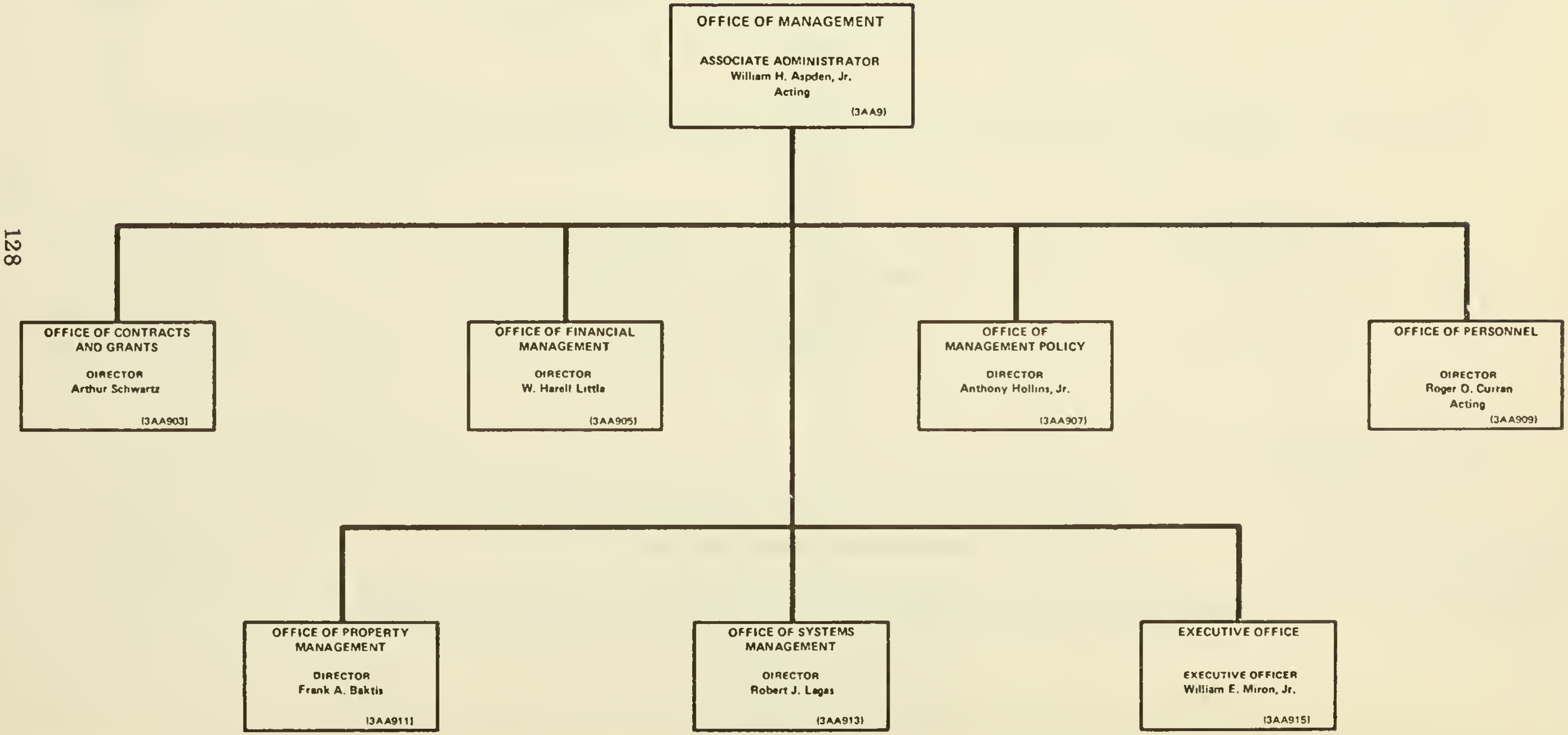
APPROVED

William H. Aspden jr

DATE. 4-14-76



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

Health Services Administration

OFFICE OF PLANNING, EVALUATION, AND LEGISLATION

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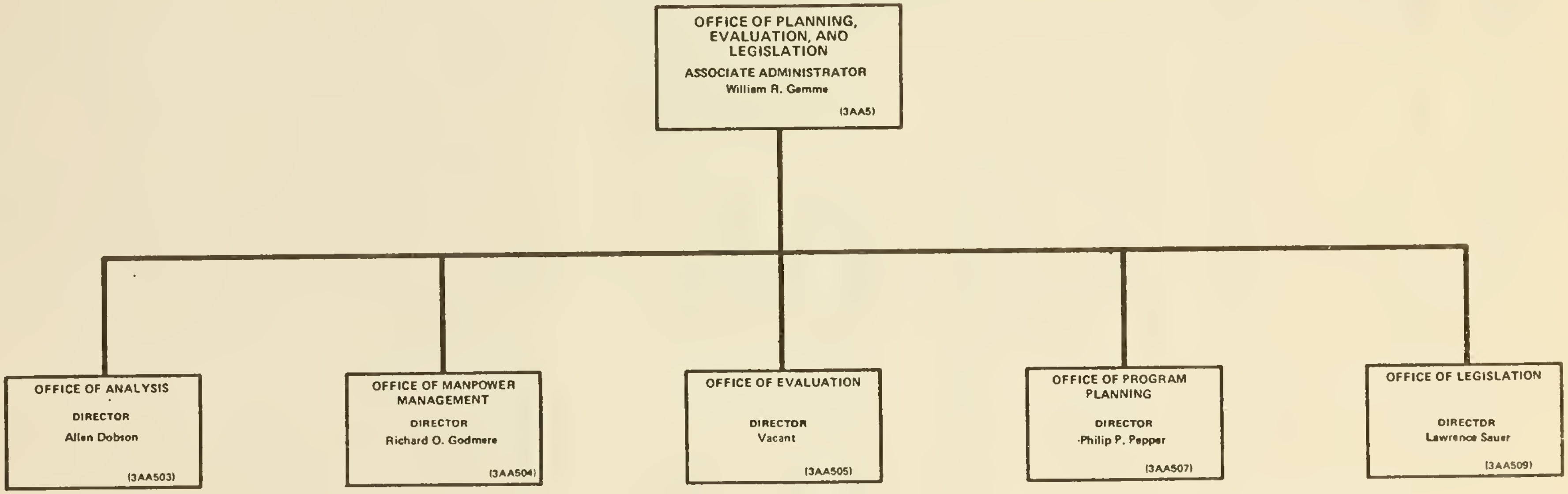

EMERGENCY MEDICAL SERVICES

GOAL: To improve the emergency health care provided to those with diabetes mellitus.

OBJECTIVES:

1. Determine the frequency of usage of emergency facilities by those with diabetes.
2. Re-classify diabetic acute emergencies as "life threatening".
3. Identify an optimal treatment plan for diabetics experiencing acute complications (both hypoglycemia and acidosis).
4. Plan, develop, and distribute appropriate educational programs for health professionals
5. Educate the public most likely to encounter such emergencies (police, fireman, teachers, school bus drivers, etc.) regarding the proper emergency treatment for a suspected diabetic patient.
6. Plan an evaluation program capable of assessing the effects of the program upon current existing care.

NEED:

There are currently approximately 10,000,000 individuals with diabetes in the U.S. Many of these citizens are susceptible to the acute complications associated with the disease and its management. These emergency conditions are hypoglycemia and acidosis.

Those being treated with insulin are most susceptible to hypoglycemia but also those on oral agents or even the early prodromata include this symptom. The lowering of blood sugar deprives the brain of its energy source and mild symptoms of hunger, trembling, sweating and headaches may give away to sleepiness, unconciousness and convulsions. Frequent, severe reactions or prolonged hypoglycemia may result in brain damage and death. Early recognition permits the patient or those around who are knowledgeable to treat the condition immediately. Patients may not be aware of the onset or may be so quickly incapacitated that they are unable to act. Uniformed or unprepared family or friends may not be able to respond to an irrational, uncooperative patient who may prevent or refuse assistance. Treatment of the unresponsive or convulsing patient only compounds the problems.

Diabetic patients come to the hospital emergency department for primary, urgent, and life threatening emergency care. Therefore a comprehensive program is required for hospital and prehospital staff to be more sensitive to the needs of the diabetic patient and also how to properly handle the different manifestations of this diseace.

Admission and treatment of the diabetic experiencing an insulin reaction is an emergency condition which requires informed and competent health professionals. Currently, diabetes admissions are not regarded as "life threatening" and their care and management is not included as part of the training program in the EMS curriculum.

Approximately 12% of diabetics admitted to hospital with a diagnosis of acedosis in the U.S. die. This is not an infrequent emergency problem among this patient population. Prompt diagnosis and therapy by emergency personnel should be able to decrease this high mortality rate. Again, diabetic acedosis should be re-classified as a life threatening condition to EMS personnel properly trained and prepared to provide appropriate therapy.

The training of the public most likely to encounter patients experiencing those acute complications will also insure their prompt treatment and diminish the serious life threatening complications associated with the disease.

PLAN:

1. Determine the frequency of diabetic patients within the emergency department environment.

   Several emergency medical service systems will be utilized to determine the number of diabetic patients that are presented at emergency departments and their needs to include such a primary care as prescriptions refills, urgent requirements to include early symptoms of diabetic coma and urgent conditions to include hypoglycemia and acidosis. It is not known how many diabetic patients are handled in the emergency system and what is the mix of conditions presented.

2. Re-classify acute diabetes as a life threatening emergency. The Division of Emergency Medical Services can re-classify acute diabetes as a life threatening emergency, in the event that a well balanced program can be developed.

3. Identify an optimum treatment plan for acute diabetic patients. One of the major problems encountered is in the correct diagnosis of the diabetic patient within an emergency environment. The young person that has been drinking and had an automobile accident can easily be diagnosed as a trauma patient with alcohol symptoms rather, than a person that has slipped into diabetic coma and has an automobile accident. Professional input is required in the field diabetes diagnosis and treatment to develop a logic plan that can be used by first responders and ambulance attendants to assist in identification of the diabetic patient and then a planned treatment protocol.

4 & 5 Develop and distribute educational materials on diabetes to help professionals working in an EMS. Educate the public most likely to encounter diabetic emergencies. A survey of literature shows that a few publications have been prepared on diabetic emergencies. If a comprehensive program can be developed the Division of Emergency Medical Services will be pleased to assist in the development of publications to highlight the need for additional attention to this

disease and to distribute such publications to first responders, health professionals and ancillary health care personnel involved in emergency medical services.

6. An evaluation program to assist the EMS impact on the acute diabetic patient. All programs supported under the Emergency Medical Services Systems Act are charged with the responsibility to develop process and impact measures to evaluate patient care. For a diabetic program, information could be collected to determine the changes in the use, frequency of care and outcome of diabetic patients in the emergency environment.

BUDGET:

To undertake the objectives outlined in this plan it is estimated that $850,000 will be required. The dollars estimated for each of the objectives are as follows:

(1) Frequency usage of emergency facilities $200,000.00;

(2) Reclassification of acute diabetes as an emergency problem - no funds are required;

(3) Develop an optimal identification and treatment program for a diabetic patient - $200,000.00 (to include the initial printing);

(4) Plan and distribute educational programs for the emergency diabetic patient - $250,00-.00 (to include initial printing);

(5) Educate the first responders regard to the proper care of the emergency diabetic patient. This objective can be accomplished within the current EMS program and with the materials developed by the earlier objectives.

(6) An evaluation program can measure the impact of improved emergency diabetic care - $200,000.00.

It is felt that all objectives could be reached within 12 to 15 months after the initiation.

Diabetes Initiative - Indian Health Service

A. Background

In most American Indian Tribes, the frequency of diabetes mellitus is much greater than among non-Indians. The Indian Health Service estimates that the number of Indian persons with diabetes mellitus, both diagnosed and undiagnosed would be in the neighborhood of 20, 000 for a rate of 40 per 1, 000 population. Diabetes ranked as the fourth leading cause of outpatient visits in fiscal year 1975 and there were 1, 859 Hospital Discharges for diabetics during this same period of time. The diabetes mellitus death rate among Indians and Alaska Natives was 24.4 per 100, 000 population compared to 13.2 per 100, 000 U.S. All races in 1974.

In a recent study of 635 diabetics on the Papago Indian Reservation in Arizona, their total illness experience as shown by clinic utilization data was compared with an age-sex- geographically matched control population. The findings showed that diabetics cause a caseload rate more than double that of nondiabetics. In 17 out of 22 broad health program areas, caseload rates for diabetics varied from 1.3 to 3.7 times greater than the rates for matched, non-diabetic controls. Workload comparisons (physician visits and hospital days) showed even greater disparity.

These data support the need for development of comprehensive clinical management programs for diabetes mellitus within Indian Health Service over and above those levels of service that are currently being provided to diabetics. Such programs could serve as models for application in other areas of the United States, especially to low income, medically underserved people.

B. Model

A comprehensive model diabetes control program is proposed that could be implemented at five service units of the Indian Health Service provided additional resources are made available.
It will

1) emphasize detection, diagnosis, and management of diabetes mellitus among high risk groups or individuals,

2) base diabetes management on staging criteria, (i.e., Diabetic Stage I., asymptomatic diabetics without remediable complications; Diabetic Stage II., asymptomatic diabetics with remediable complications; and Diabetic Stage III., symptomatic diabetics with or without remediable complications),

3) make use of trained paramedical workers (community health medics - physician's assistants, dieticians, pharmacist practioners, public health nurses, community health representatives) to a major extent in the management of asymptomatic diabetics, so that physicians can give greater attention to diabetics with symptoms and remediable complications,

4) stress that early diagnosis and careful management of diabetic pregnancies can markedly reduce the complications of spontaneous abortion, stillbirth, neonatal death, congenital malformations, and macrosomia.

Based on the recommendations of the Diabetic Subcommittee of the Indian Health Service, the IHS internists have proposed the following standards (or guidelines) for diagnosis and management of diabetes mellitus.

Subjective:

History (initially and at least annually thereafter) regarding:

1. Conditions attributable to elevated plasma glucose levels (polyuria, polydipsia, weight loss, pruritis).
2. Symptoms or past history of sensory or motor neurologic abnormality.
3. Symptoms or previous diagnosis of urologic disease or vaginitis.
4. Symptoms or prior diagnosis of cardiovascular disease.
5. For women: Obstetric abnormality (delivery of infant $\geq$ 9 lbs., stillbirth, neonatal death, infant with congenital malformation, toxemia of pregnancy, spontaneous abortion).
6. Diabetes in near relatives (parents, siblings, children).
7. Acute visual disturbances.

Objective:

1. Diagnostic criteria:

    a. All men and nonpregnant women:

        1. Preferably, modified glucose tolerance test (GTT), with determination of plasma glucose (PG) at two hours after loading; $\geq$ 200 mg./dl., diabetic (if confirmed by additional test); $\leq$ 179 mg./dl., nondiabetic; 180-199 mg./dl., indeterminate. (Repeat test if in this category.)

        2. Alternatively acceptable, either two fastings PGs $\geq$ 160 mg./dl. or two two-hour postprandial PGs $\geq$ 200 mg./dl.

    b. Pregnant women (more liberal criteria):

        1. First or second trimester -- two hour GTT PG $\geq$ 140 mg./dl.

        2. Third trimester -- two-hour GTT PG $\geq$ 160 mg./dl.

2. Evaluation (performed initially and annually thereafter); a standardized minimum examination including but not limited to the following:

    a. Height (initially only), weight, per cent desirable weight.

    b. Blood pressure.

    c. Ophthalmoscopic examination.

    d. Peripheral pulses (palpation).

    e. Skin examination (especially lower extremities).

    f. Electrocardiogram (12-lead), for patients $\geq$ 40 years of age (every five years).

g. Neurologic examination (vibratory, touch, deep-tendon reflexes of lower limbs).

h. Serum creatinine or blood urea nitrogen.

i. Urinalysis (albumin, acetone, glucose).

j. PPD skin test (annually, if negative; if positive, obtain chest x-ray instead. Recommended because of high rates of tuberculosis in southwestern Indian diabetics.)

Assessment:

Based on these evaluations:

1. Diagnoses include:
   - a. Diabetes mellitus.
   - b. Diabetic complications (renal, cardiovascular, neurologic, optic, infectious, obstetric).
   - c. Other contribuing conditions (obesity, pregnancy).
2. Diabetes staging for purposes of management recommendations (table 1):
   - a. Asymptomatic diabetes without remediable complications.
   - b. Asymptomatic diabetes with remediable complications.
   - c. Symptomatic diabetes with or without complications.

Plan (management):

1. Dietary management and weight control for all diabetics, especially stressed for overweight patients.

2. Hypoglycemic therapy (preferably insulin), for the symptomatic or the asymptomatic diabetic with a complication in which the maintenance of normoglycemia may be indicated in the management of that complication.

3. Management of complications (by appropriate specific or symptomatic therapy);

4. Pregnant diabetic (requires careful management, including meticulous control of plasma glucose levels):

   a. Keep two-hour PG $\leq$ 160mg./dl.

   b. Avoid hypoglycemia and ketosis, both deleterious to fetus (requires feeding frequently, avoiding prolonged fasts, and, even with obesity, restricting daily diet to no less than 1,500-2,000 calories).

   c. When hypoglycemic therapy is required, insulin is currently the only acceptable agent.

   d.. Specialist (obstetrician/internist) referral for any complications, failure to maintain normoglycemia, infection, or intercurrent illness.

5. Management by "stage" (see table 1).

TABLE 1

Minimal management of diabetes mellitus based on stages

Diabetic Stage	Management		
	General	Other	Routine
I. Asymptomatic diabetics without remediable complications.*	Patient to see PHN/CHM/CHR** every 3 months for history, weight, and urinalysis; referral to physician, if changes occur.	Physician to see patient at least annually.	Annual diabetes examination (See text team no. 2. "Evaluation").
II. Asymptomatic diabetics with remediable complications.*	Physician to institute specific therapy for complications.	Physician to see patient at least every 3 months.	Annual diabetes examination.
III. Symptomatic diabetics with or without remediable complications.	As for II; also physician to see at least every 3 months for hyperglycemic control, symptom inquiry, weight, blood pressure, urinalysis.	If patient goes 1 year without symptoms, and no remediable complication, may see physician every 6 months and follow schedule of I otherwise.	Annual diabetes examination.

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* Remediable complication: Infections, hypertension, congestive heart failure, arrhythmias, acute neuropathy, peripheral vascular disease (leg ulcers, incipient gangrene); mature cataracts, (?) retinopathy, pregnancy. Nonremediable complications: nephropathy, chronic stable polyneuropathy, autonomic neuropathy.

** PHN=Public health nurse; CHM=Community Health medic (or physician's assistant); CHR=Community health representative.

6. Diabetes case finding:

   a. Recommended frequency of glucose tolerance testing, based on diabetes prevalence in the local service-unit population aged $\geq$ 35 years (varying by age group):

      1. High prevalence ($\geq$ 35 per cent) -- at five-year intervals for persons aged 15-29 years and $\geq$ 50 years; at two-year intervals for persons 30-49 years.

      2. Medium prevalence (15-34 per cent) -- at five-year intervals for persons aged $\geq$ 30 years, once at leaving high school for females 15-29 years.

      3. Low prevalence ($\leq$ 14 per cent) -- once during ages 30-49 years, only when high risk (see item "b" below) during ages $\geq$ 50 years or $\leq$ 29 years.

   b. Other specific conditions in which diabetes screening is considered appropriate, based on known risk factors for diabetes:

      1. Obstetric abnormalities -- infant $\geq$ 9 lbs. at birth, stillbirth, neonatal death, congenital malformations of offspring, toxemia of pregnancy, or spontaneous abortion.

      2. Diabetes family history (order of priority: both parents, one or more siblings, one parent).

      3. Gross obesity ($\geq$ 150 per cent desirable weight).

      4. Coronary heart disease, periphereal or cerebral vascular disease.

      5. Periphereal neuropathy and cranial (motor or sensory) neuropathy.

      6. Active tuberculosis.

      7. Recurrent infections, especially vaginal moniliasis

      8. Hypertension

      9. Proteinuria of unknown cause

      10. Hyperlipidemia (cholesterol $\geq$ 250 mg./dl.; fasting triglyceride $\geq$ 200 mg./dl.).

      11. Acute refractive eye changes.

The guidelines presented are intended to define minimum acceptable standards of care for American Indian diabetics and to encourage the development of systematic and cost-effective methods of diabetes management and detection at the individual service-unit level. Utilization of the guidelines also demands a responsible attitude, with alertness to matters beyond the scope of the standards. Complications of the disease or contributory factors may require individualized diagnosis and management. Nevertheless, the guidelines should provide a structure to enhance rational approaches to the problem of diabetes, in regard to both the individual patient and the public-health aspect.

Although tailored to the organization and mission of the Indian Health Service, the guidelines may be useful to other groups responsible for the diagnosis and management of diabetes or for broader community or public-health activities. The general outline can be modified to the requirements of other health-service organizations. In particular, the systematic utilization of nurses, physicians' assistants, dietitians, community health workers, and other paramedical personnel in the care of diabetic patients should be beneficial not only to the Indian Health Service but also to a variety of other health systems.

C. Methodology

1. Prior to the selection of any service unit for a diabetes control program, the Area Director (and/or Chief Area Medical Officer) and consultant internist (if desired) meet with the local Indian tribal health board and explain completely the program that is proposed. Tribal approval must be obtained and a letter or resolution will be required before any program can start.

2. The first part of the study involves a diabetes prevalence study as described in B.6 above, diabetes case finding. This phase would involve the physician/director of Diabetes Program (prefereably an internist), Public Health Nurse, Health Educator, community health medic (CHM) and community health representatives (CHR's). Laboratory personnel, outpatient nursing staff, and health records secretaries will be responsible for blood studies, EKG's, and maintenance of records.

3. Those patients found to have diabetes will be managed according to "staging criteria" in Table 1, above. This management will include treatment and referral for remedial complications and interrelated conditions. In addition to the personnel described in C.2 above, the nutritionist/dietician, podiatrist, and pharmacist assume critical roles in the management of the patients.

4. Each patient will have his own treatment plan and will be counseled by the physician, public health nurse, and community health medic. Appointments will be made for appropriate followup visits and transportation arrangements will be confirmed. All diabetic patients will have at least an annual diabetes examination.

5. All diabetic patient records will be reviewed monthly by the health records clerk to follow up on whether appointments have been kept, results of tests have been seen and confirmed by the physician, and to send out appointment reminders as necessary.

6. Data will be integrated into the IHS computerized patient records system and analyzed every six months by the Area Director (Chief Medical Officer) and the physician/director of the diabetes program. The results of this review will be shared with all participating Diabetes control program team members and with the Senior Clinician Internal Medicine, Indian Health Service.

7. Annually, an evaluation of all IHS Diabetes Control programs will be made by a team of outside expert consultants (National Diabetes Advisory Board Members) who will review the program reports together with the Senior Clinician Internal Medicine IHS, and Area and Service Unit personnel. This team will prepare a report on their findings and recommendations. Appropriate adjustments can then be made by programs and the agency in response to this evaluation.

D. Workplan

1. Secure necessary tribal approvals. (1-2months.)

2. Recruitment of multispecialty staff (6 months.) This includes orientation and training of all new staff for two weeks.

3. Diabetes Prevalence Study (2 months).

4. Diabetic Control Program start up. Treatment/Management begins according to "Staging Criteria" (8-10 months after startup and thereafter for one year.)

5. Six month Evaluation by Area Director (Chief Medical Officer) and physician director. (6 months after startup.)

6. Annual evaluation by outside expert consultants and response to recommendations (12 months after startup.)

7. Continuation of program.

It will be noted that approximate time from D.1 through D.6 is 20 to 22 months of time. Startup cannot occur until sufficient additional staff is recruited to carry out the proposed additional responsibilities.

It is proposed to develop 5 such model diabetes control programs for completion within two years after resources are made available.

Proposed sites for these programs are:

	Diabetes Control Program Service Units	Control Service Units
North Plains:		
	Rosebud	Pine Ridge
	Rapid City	Sisseton-Wahpeton
Oklahoma:		
	Claremore (or Lawton)	Lawton (or Claremore
	Talihina	Tahlequah
SW:		
	Sells (or Sacaton)	San Carlos (or Sells)

Assuming the successful completion of these 5 programs and the availability of additional resources, approximately 5 additional programs can be started the third year, 5 more the fourth year and 5 more the fifth year. This would bring the total to twenty (20) IHS Diabetes Control

Programs in operation at the end of the fifth year. To meet the total needs for such programs within IHS would require a second 5 year period with the establishment of 6 new programs each year, until a total of 50 programs are operational at the end of 10 years. This should establish Diabetic Control Programs in the Service Units with the greatest need for such programs.

E. Training

It is not expected that personnel will be recruited at the same time so that a single training session would be impossible. It is also not feasible to establish the position of full time training coordinator and separate training sites for five programs in three different areas. Therefore, it is proposed to send all new personnel to Phoenix Area, where they can participate in an ongoing training program for Community Health Medics and work with diabetic patients under the supervision of appropriate clinician trainers. Consultants can be made available to assist in this training on a regular basis.

If resources are made available to establish 50 Diabetes Control Programs, the position of overall IHS Diabetes Training Coordinator can be established which can be attached to a single site within one area or rotated through different areas according to the particular area needs for such training at any given time.

F. Research

Diabetes Research Programs are separately funded through the National Institutes of Health. To date, such research efforts are largely concentrated in the Phoenix Area and in the Oklahoma Area. It is suggested that more research be directed at Northern Plains Indians, and that increased research efforts are made to determine the differences in "Indian Diabetes" from non-Indian Diabetes. All research programs require local tribal and service unit and area office approval. Documents attesting to this approval are required by the Area Research Committee.

Appropriate interagency agreements between the Tribe, the Indian Health Service, and the Research Unit must be signed before actual research can be initiated. All compliance with Protection of Human Subjects and Informed Consent regulations will be observed.

All information collected in a research project will be safeguarded under the Freedom of Information Act.

G. Budget for First Year

A. For One Service Unit

Personnel

1	Physician/Director	- G.S. 15 or C.O. 5	$ 35,000
1	Field Public Health Nurse or Health Educator	- G.S. 9/10	15,000
1	OPD nurse	- G.S. 8	12,000
2	Community Health Medics	- G.S. 7-9	25,000
1	Podiatrist	- G.S. 11	17,000
1	Laboratory/EKG Technician	- G.S. 7	11,000
1	Nutritionist/Dietician	- G.S. 11	17,000
1	Pharmacist	- G.S. 9 or C.O. 3	13,000
1	Secretary/Health Record Clerk	- G.S. 6	10,000
10	Positions Total	@	$ 155,000

B. For Five Service Units

50	Positions Total	@	$ 775,000

Equipment

A. For One Service Unit

1	Beckman Analyzer	$ 14,000
1	Ames Reflectance Meter	400
1	EKG machine	1,000
	Additional ophthalmoscopes, stethescopes, sphygmomanometers, syringes, needles, drugs, office supplies	1,600
	Total	$ 17,000

B. For Five Service Units

B. For Five Service Units	$ 85,000

Training

A. For One Person

16 days per diem @ $40.00	=	$ 640.00
Round Trip Air Travel to Phoenix	=	350.00
Average Cost of Supplies/Trainee	=	100.00
Total		$ 1,090.00

B. For 50 Persons

Total	$ 54,500
Consultation Costs (Includes all travel, per diem, and fees)	$ 10,000
Grand Total	$ 64,500
A. Total Budget for One Service Unit	$184,900
B. Total Budget for Five Service Units	$924,500
Total First Year Funding Required	$924,500

Budget for Second Year

Continuation of Personnel for Five Service Units	$775,000
Evaluation Costs	10,000
Total Budget for Second Year	$785,000

Budget for Third Year

Continuation of Personnel	$ 775,000
Evaluation Costs	20,000
Five Additional Programs	924,500
Total Budget Third Year 50 positions and	$ 1,719,500

Budget for Fourth Year

Continuation of Personnel	$ 1,550,000
Evaluation Costs	30,000
Five Additional Programs	924,500
Total Budget Fourth Year 50 positions and	$ 2,504,500

Budget for Fifth Year

Continuation of Personnel	$ 2,325,000
Evaluation Costs	40,000
Five Additional Programs	924,500
Total Budget Fifth Year	$ 3,289,500

Grand Total Resources Required for 20 Diabetes Control Programs Phased over Five Years

200 Positions and	$ 9,223,000

H. Proposed Method of Funding

Funding for the proposed Indian Health Service Diabetes Initiative should be provided to IHS. If such funds are to be made available by another Federal agency, such as the National Institutes of Health, a cooperative agreement calling for a transfer of funds can be used.

Also, if in the future, the Commission recommends additional funding for other Federal agencies/States for service programs, in particular, the Commission should be aware of the need to provide for a "set aside" for direct funding to tribes.* This recommendation is based on the historic neglect that has occurred when States, in particular, receive funds to serve the total population, including Indians. Indians are counted to increase the State's share of the funding, but Indians almost never see anticipated services or other benefits.

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* Tribes are considered units of State and local government and as such receive General Revenue Sharing and CETA grants.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES ADMINISTRATION
BUREAU OF QUALITY ASSURANCE

TO : National Commission on Diabetes

DATE: September 8, 1976

FROM : Director

SUBJECT: Proposed BQA Assistance to National Commission on Diabetes

The Bureau of Quality Assurance (BQA), Health Services Administration, has offered to assist the National Commission on Diabetes in three primary areas. The first two areas related to the performance of a Medical Care Evaluation study of Diabetes. The third general area relates to the management of all diabetes related information.

The Medical Care Evaluation (MCE) study will have as its purpose the evaluation of the present quality of care of diabetics. To assay quality, a list of criteria of care will have to be established for the specific diabetes-related topic(s) under evaluation. The Commission will meet to determine which specific topic is to be evaluated. BQA can then assist the Commission in choosing the appropriate source of criteria. The American Medical Association (AMA) has recently completed a million dollar contract, sponsored by BQA, for the development of disease-related MCE criteria. The American College of Physicians and the American Society of Internal Medicine were asked to write criteria for the following MCE topics:

1. "Diabetes Mellitus"
2. "Diabetic Coma and Pre-coma"
3. "Diabetic Chronic Complications"

In addition, the American Academy of Pedicatrics wrote "Diabetes Mellitus, Juvenile." BQA proposes contacting appropriate professional societies and groups, on behalf of the Commission, for the preparation of criteria for more specific diabetes care related topics.

The second proposal involves our assistance in developing Diabetes MCE performance sites. By law, BQA cannot dictate that any PSRO or hospital perform any specific study. Most PSROs are already strained to meet present MCE requirements. However, to encourage diabetes studies, BQA could offer the predetermined criteria developed above to any interested PSRO. Beyond this, PSROs might be encouraged to participate in the National Diabetes MCE through the auspices of the American Association of PSROs (AAPSROs). By contracting the administrative services of AAPSRO, the Commission could assure that the study is performed in a statistically significent number of sites with variable background. BQA will assist AAPSRO as necessary.

A third general area in which the Commission and the Bureau could pursue common goals is that of medical practice information. There is, of course, a great deal of information relating to the epidemiology, diagnosis, and treatment of diabetes and its various complications. Some of that information is grounded in well-designed basic scientific and clinical studies, some based on years of clinical experience and judgment, and some likely based solely on dogma. The validity of each piece of information is likely related to its source, i.e., scientific knowledge, clinical judgment or dogma, and is probably highly variable. In addition, information relating to any one aspect of diabetes is likely to be contradictory. A case in point is the treatment of the infected foot of the diabetic patient. Despite the prevalence of the problem of the diabetic foot and despite research into its treatment, no generally agreed upon method of treatment exists. What would thus appear worthwhile for the practitioner would be a compilation of the best information available relating to the epidemiology, diagnosis, and treatment of various aspects of diabetes, and an estimate of the validity of that information.

In a project now in its infancy and directed from the Office of the Assistant Secretary for Health, BQA in conjunction with the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), the National Cancer Institute (NCI), and the National Heart, Lung and Blood Institute (NHLBI), is attempting to demonstrate whether "best information" can be developed and whether that information can be validated. The undertaking, termed the Medical Practice Information Demonstration Project, has tentatively selected as its study topics: depression, breast cancer, and hypertension. The method to be utilized is expert group consensus. Basically, it requires the institutes involved to select persons knowledgeable in the topic area and with specific knowledge in its epidemiology, diagnosis treatment, costs, prevention, etc. Those persons then nominate other experts in the topic area who serve as the expert group. Through a structured method already developed, the experts are separately asked to identify the best information source. That information is then collected. Subsequently, in a meeting of the experts, a validity rating, based on predetermined criteria, is attached to each piece of information. The final product will be a report outlining the information in each topic area, along with its validity rating and the documentation (reference) supporting the information.

How this project and the interests of the Commission might meet lies in the addition of diabetes as a topic area, with the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) as the involved Institute. Project costs for the Institute's share of the project development and for a single study topic would be in the range of $50,000-$100,000. We would suggest this as a method by which the Commission and BQA could further their common goals with the Commission recommending the appropriation of these funds for the study and using its auspices to encourage the participation of NIAMDD.

Michael J. Goran, M.D.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES ADMINISTRATION
Bureau of Community Health Services

TO : Associate Administrator
for Regional Affairs
Through: Director EDM

DATE: September 1, 1976

FROM : Chief, Quality Improvement Branch, DCS and
Acting Director, Office of Program Development

SUBJECT: Follow-Up of Meeting with Diabetes Commission Sub-groups on Service Issues August 25, 1976

As agreed, we discussed the several suggestions emanating from this meeting with Dr. Martin. Following is a summary of BCHS reactions and suggestions. Perhaps you could modify and transmit these suggestions to the sub-group as you think appropriate.

1. Projects for Juvenile Diabetics

To adequately address the needs and problems of the estimated 86,000 juvenile diabetics, the project grant approach does not seem to be feasible at this time. Reasons include the numerous specialized projects BCHS is presently administering with a staff limited in numbers and the subsequent need to contain the current spectrum of activities in order to improve the effectiveness and efficiency of programs already in operation. At a later time, this suggestion could be reconsidered. The Commission might wish to consider the alternative of increased funding for state crippled children services (Title V, SSA) to provide for the extension and improvement of such services to more children who have diabetes.

The State crippled childrens programs offer the possibility of providing for the specialized care needed by such children. Increased funding could also facilitate the provision of more comprehensive services to diabetic children (public health nursing, nutrition, social work, etc.), and provide for linkages with primary, secondary and tertiary levels of care, etc. At the present time, because of fiscal constraints, States are finding it necessary to limit diagnostic categories of handicapping conditions and the range of services provided.

2. Development of educational materials for providers, patients and the general public

There is a considerable amount of material already developed and we feel that it is important to make maximum use of available resources. A National Clearinghouse for Diabetes could facilitate this process. As gaps or special needs are recognized in the service delivery programs, the Bureau will interpret them and cooperatively work with CDC and NIH to develop and disseminate the necessary educational materials.

3. In-service training/continuing education for Health Care Providers

Providers in the primary health care programs administered by the Bureau receive continuing education/in-service training in varying amounts and ways. The diabetic component of such training might be reviewed and strengthened as indicated. The BHM/HRA should have the lead in this activity since they are already involved in the training provided for the NHSC assignees. BCHS would work cooperatively with them in relation to the diabetes component of such training.

4. Model for strengthening the "comprehensiveness" of total community primary care provided for diabetics

The urgent needs of the older patient with diabetes for services in nutrition, medical social service, public health nursing, etc. is recognized. The fact that such services are not available to many patients is also known. The possibility of developing 1 - 2 community models based on an existing primary care system which would extend such services to the broader community could be explored. e.g. Such services might be made available through a county health department on a fee-for-service basis to the patients of private physicians.

Another model might use the state crippled children program to extend the needed specialized services to the private physician and CC program personnel involved in providing specific aspects of care, e.g. special needs of adolescent diabetics. BCHS could take the lead in exploring the development and implementation of 1 - 2 such models.

Paul East

Paul East, M.D.
Mary C. Egan

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION
BALTIMORE, MARYLAND 21241

BUREAU OF
DISABILITY INSURANCE

REFER TO

August 12, 1976

Oscar Crofford, M.D.
Chairman
National Commission on Diabetes
Garrett Park, Maryland 20766

Dear Sir:

Approximately three weeks ago, the Commission transmitted the Report "The Long-Range Plan to Combat Diabetes" to James B. Cardwell, Commissioner of Social Security. Particular attention was directed to pages 44, 46, and 79 of that Report. I am responding to those issues for Commissioner Cardwell.

The first issue (page 44) conveys the Commission's recommendation to the Secretary of Health, Education, and Welfare that each agency director be instructed (1) to prepare a report within six months with (a) complete lists of services and resources available in his agency to meet the needs of the patient with diabetes and with (b) proposals of how these and additional resources may be used for diabetes in light of the long-range plan to combat diabetes. This material is being prepared.

The second issue (pages 46 and 79) conveys the Commission's recommendation that the Social Security Administration modify the guidelines for reimbursement of patients with diabetes to ensure that all items of patient education expenses are included as reimbursable elements of patient care. The response to this issue is discussed in the attachment to this letter. I believe that the statement is responsive to the recommendation. Please let me know if further information is required. I may be reached at (301) 594-1770.

Sincerely,

Herbert L. Blumenfeld MD

Herbert L. Blumenfeld, M.D.
Acting Chief Medical Officer
Bureau of Disability Insurance, OPO
Social Security Administration

Enclosure

Issue: The National Commission on Diabetes recommends that SSA modify its guidelines for reimbursement of patients with diabetes to ensure that all items of patient education are included as reimbursable elements of patient care. The commission states that the most negative factor is the policy not to include all patient education for diabetes as a reimbursable item.

We would like to point out that the Medicare law permits reimbursement for physicians' (physician-directed clinics) services and services and supplies furnished incident to a physician's service, and services furnished by hospitals, skilled nursing facilities and home health agencies; these services must be reasonable and medically necessary for the treatment of and individual's illness. To be reimbursable under Medicare, educational services must also be directly related to the care and treatment of the patient's diagnosed illness.

In many instances educational services required by a patient in connection with the treatment of his or her illness do not necessitate the patient's involvement in a highly concentrated and formally structured type of educational program, but rather are included and reimbursable as a part of the basic care and treatment being furnished by the health professionals involved in treating the patient. However, in some instances the instructions needed are of such complexity that a highly concentrated and formally structured educational program may constitute the most effective means of providing a patient with the instructions which are necessary to the effective treatment and management of his or her medical condition. The educational services required in these latter instances are covered under Medicare where pertinent coverage requirements and tests of reasonableness are met, i.e., such a structured program is necessary to the treatment of a particular diagnosis, reasonable and necessary to the patient's particular condition, and reasonable in content.

Generally, because of the number and complexity of the services required in the treatment of diabetes, such a structured program would be considered reasonable and necessary to the treatment of a diabetic. However, as indicated the content of such programs must also be reasonable and necessary, i.e., such programs should meet but not exceed the needs of such patients. For example, some programs may provide a more extensive theoretical background of the illness than needed. While patients do require a certain amount of understanding of the pathology involved in their illness, the emphasis, in any program, should be on providing the patient with practical knowledge (e.g., dietary counseling) and skills (e.g., how to self-administer injections) necessary for successful treatment. Theoretical education (e.g., pathology, etiology of illness) would be covered only to the extent that the patient needs such knowledge to actively participate in the treatment process. In addition, some programs may provide information which would be of interest to the patient but which is not essential to the management of his condition, e.g., research related to diabetes, employment and insurance for diabetics, etc. However, reimbursement for the provision of such information is not properly within the domain of Medicare, a health insurance program.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL AND REHABILITATION SERVICE
WASHINGTON, D.C. 20201

OFFICE OF THE ADMINISTRATOR

AUG 1 1 1976

Oscar Crofford, M.D.
Chairman, National Commission on Diabetes
P.O. Box 225
Garrett Park, Maryland 20766

Dear Dr. Crofford:

I want to commend you and the National Commission on its indepth study and Long-Range Plan to Combat Diabetes. The Social and Rehabilitation Service (SRS) is pleased to have participated on the Diabetes Mellitus Coordinating Committee and will continue to cooperate in its efforts towards more efficient utilization of all Federal health resources.

I would like to respond to the Report recommendations concerning the SRS as noted on page 44, 46, and 79. The recommendations direct SRS Agencies to develop guidelines concerning reimbursement and services specific to diabetic individuals.

By statute, SRS programs must provide all services to all eligible individuals, the determination being made on basis of income, need and category and not by virtue of disease diagnosis.

Eligibility limitations for medical assistance under Title XIX are set by statute and State selections from certain options. The same services must be available for all eligible individuals (except for certain specified exceptions in the statute not pertinent here). There may be no arbitrary distinctions on the basis of the diagnosis, type of illness or condition for the required medical services (45 CFR 249.10 (a)(5).) As a result, an eligible diabetic has the same coverage as an individual with any other condition, dependent of course on medical necessity for such care.

As to reimbursement for "all elements of patient education", such services are presently reimbursable to the physician as physician services, provided they are carried out by or under the supervision of the physician.

Summary descriptions of the three major SRS programs and their activities relevant to Diabetes Mellitus is attached for your convenience.

If SRS can be of any further assistance or if you have any questions, please feel free to call on me.

Sincerely yours,

Robert Fulton
Administrator

Enclosures

cc: Dr. Keatha Kruger

VETERANS ADMINISTRATION
OFFICE OF THE ADMINISTRATOR OF VETERANS AFFAIRS
WASHINGTON, D.C. 20420

AUGUST 12 1976

Dr. Oscar Crofford
Chairman
National Commission on Diabetes
P. O. Box 225
Garrett Park, MD 20766

Dear Dr. Crofford:

This is a response to your letter received July 1, 1976, requesting from the Veterans Administration a statement of progress relative to the National Commission on Diabetes report, "The Long-Range Plan to Combat Diabetes," submitted to Congress on December 10, 1975.

The Report of the National Commission on Diabetes recommended that the Administrator of the Veterans Administration increase the programs of the Agency in the areas of research, education and treatment in diabetes mellitus. In addition, the Commission believes the following special programs should be considered by the Veterans Administration:

- Establishment of special units for the development of new modes of therapy for diabetes

- Cooperative studies of the efficacy of present modes of therapy for diabetes

- Manpower training in diabetes (medical and paramedical)

- Project research in diabetes

- Funds for these diabetes programs should not come out of, nor compete with, the general VA budget, but should be additional funds specially designated within the VA budget request to the Congress.

Dr. Oscar Crofford, Chairman
National Commission on Diabetes

The details of VA activities in research, education and treatment of diabetes mellitus have been given in the reports of the Diabetes Mellitus Coordinating Committee, which, along with the Commission, was created by Public Law 93-354, the National Diabetes Mellitus Research and Education Act. The VA has profound involvement in diabetes mellitus as an essential part of the VA medical mission to provide the best medical care to veterans.

The report of the National Commission on Diabetes to the Congress was made in December 1975, therefore, the recommendations were not available for consideration in the VA budget preparation for fiscal years 1976 or 1977.

Special programs that are for VA consideration, as included in the report, are commented on as follows:

- The VA believes that diabetic patients are usually better treated in high quality units delivering general care. Special units for the development of new modes of therapy for diabetes are not considered as an appropriate mechanism by which the VA would provide comprehensive quality care to veterans. The Agency does, however, operate over 1,200 specialized units within our general care facilities having relevance to research, education and treatment of diabetes mellitus. These units are an integral part of health care designed to meet the needs of different levels of care rather than of specific disease entities and include: specialized diagnostic and treatment units, cardiac catheterization units, hemodialysis units, transplant units, intensive care units and coronary care units.

- Cooperative studies of the efficacy of present modes of therapy for diabetes may be performed as VA cooperative studies. Such studies are initiated by VA investigators and clinicians in our health care facilities who are associated with the affiliated institutions and are not initiated by a centralized request for proposals. The VA and the country has been well served through significant major advances in prior VA cooperative studies using this procedure.

- Manpower training in diabetes (medical and paramedical) is an integral portion of the VA's large responsibility in health care, education, and training programs. During the past fiscal year, these manpower programs included over 82,000 individuals using VA facilities. The VA is a part of the national trend away from high specialization in training programs especially those involving medical residents and medical students. Training in diabetes mellitus treatment is an integral part of any comprehensive curriculum.

- Project research in diabetes is not planned as a categorical disease-directed topic within the VA. Research within the VA is approved and funded on the basis of merit, quality, scientific validity, and having a relevance to the veteran population served. It is important that the total funds available for research within the VA remain administratively flexible in order to select projects of the highest quality. Our prior and current experiences demonstrate that our research is best when not directed by category. Included with high frequency are projects relating directly and indirectly to diabetes mellitus and we anticipate that the importance of this disease to the veteran patients will maintain its study at the forefront of our scientific activities.

Dr. Oscar Crofford, Chairman
National Commission on Diabetes

We appreciate the opportunity to participate in this effort. If you have any questions, please call Dr. Herbert Baganz, 389-3550.

Sincerely,

RICHARD L. ROUDEBUSH
Administrator

COMMUNITY PSYCHOLOGICAL SUPPORT SERVICES FOR JUVENILE DIABETICS

Dr. Lenore Behar
Chief, Child Mental Health Services
North Carolina Division of Mental Health Services

I. Usefulness of psychological support services for juvenile diabetics, their families, and their community:

A. To help child develop mechanisms to cope with the disease that also represent healthy adaptations to family, peers, school, social environment.

B. To help child maintain healthy self-concept.

C. To help child adjust to disease so that psychological defenses not interfere with medical management of disease, (e.g. so that child's feelings do not influence maintaining proper diet).

D. To help family (parents) cope with their feelings so that they can contribute positively to child's personal, social, and medical adjustment to diabetes.

E. To help others in child's life understand his illness so they may also contribute positively to his adjustment.

II. A possible delivery system might include the following:

A. A team of child counselors (psychologist, psychiatrist, psychiatric social worker, special education teacher, or nurse) and a parent counselor (similar professions) each to provide group counseling sessions. (For a population of 200,000, based on statistics of one juvenile diabetic in 600, one child group leader and one parent group leader are needed.)

1) Children will be offered two group programs per year (8 months apart) with each program meeting two hours weekly for two months. The purpose of the group session (of 8-10 children) will be to discuss feelings about having diabetes, how it influences how child feels about himself, how it influences his reactions to family friends, school, etc. Counseling will be reality oriented with leader and children working toward mutual support, sympathy, and understanding and focusing on recognition of appropriate behaviors and encouraging healthy responses rather than maladaptive ones.

A second purpose of the group sessions will be for the leader to help identify children who might need more intensive psychological services, or for children who want more service to have opportunity to ask for it.*

2) Parents will be offered a group counseling program of the same duration as the child's. The purpose will be to help parents understand their own reactions - guilt, tendencies to over-indulge, over-protect, disappointment in child, etc., so that they can better control the influence of these feelings on parent-child interaction and on child's adjustment - as well as their own. As with child counseling group, these two month sessions will also provide opportunity for identification of those who want or need further, more intensive counseling.*

B. A project coordinator and evaluator to provide psycho-diagnostic/evaluative services; to serve as liaison to medical staff; to provide, with child and parent counselor, educational services to teachers and others involved with child.

1) In order to assess psychological adjustment in parent and child and to document change as the result of the program, the evaluator will gather information on the following (Using existing standardized instruments):

a. In the child -

1) Self concept and personal adjustment
2) Parent-child and child-sibling relationship
3) Academic adjustment
4) Social adjustment
5) Adjustment to the medical constraints placed on him/her, obtained through an evaluation form (to be developed) provided by the physician.

b. In the parent -

1) Self concept and personal adjustment
2) Parent-child relationship
3) Marital adjustment

---

*The leaders could provide either continuing group or individual counseling or could refer to other local resources depending on the client's needs and caseload.

2) These measures, obtained pre and post each of the two programs should indicate change. In order to further clarify the agent of change, the following design is suggested:

Using groups of children matched for age, race, sex, age of onset of disease, severity, and hereditary factors, assign as follows:

Group A - Children and parents receive counseling; measures obtained on parents and child.

Group B - Only children receive counseling; measures obtained on parents and child.

Group C - Only parents receive counseling; measures obtained on parents and child.

Group D - Neither parent nor child receive service, but measures listed above obtained.

The crucial variable is documented change in child's level of adjustment, as measured by standardized instruments and physician's appraisal. Existing computer storage and programs would be adequate for these measures, and data analysis.

C. For communities larger than 200,000, additional staff can be added - basic staff of three, plus secretary and other project costs should be approximately $55,000 or about $500/year/child - based on approximately 110 diabetic children/66,000 or 66,000 children/200,000 population.

For smaller communities, the staff can be mobile, following a circuit riding concept, serving two or three communities, or can be staff of hospitals, clinics, mental health centers, or even large school systems, that provide services to other kinds of clients as well.

D. The number of pilot projects is limited only by funding; sufficient feasibility data should be available from 6-10 projects.

III. A coordinating office seems indicated to provide technical assistance, data pooling, general trouble shooting, back-up support and a talent bank of specialized consultants, so that all projects are getting similar information and advice. Also could organize quarterly coordinating meetings to share information and to provide on-going training to project staff.

Costs for such an office, within a Federal agency or office of a national organization should be at most $100,000, including funds for program consultants and funds for the development of relevant materials such as audio visual materials for group sessions.

POSSIBLE APPROACHES FOR PSYCHOLOGICAL RESEARCH, TRAINING, AND CLINICAL SERVICES WHICH MAY BE CONSIDERED BY NATIONAL DIABETES RESEARCH AND TRAINING CENTERS

Submitted by

Joan W. Hoover, James W. Young and David M. Holmes, M. D.

I. Research

The Diabetes Research and Training Centers may undertake research which investigates the psychological aspects of diabetes as a chronic illness and how these relate to management and the clinical course of the disease. If the Centers should choose to include such a component. the following are suggested approaches for its implementation.

A. Distinguishing between juvenile and maturity-onset diabetes, such psychological research could be directed toward:

1. The personality structure and quality of psychological functioning which characterizes the patient at the time of diagnosis. Particular attention should be paid to the patient's age and stage of psychological development at this time, as an indication of the manner in which the patient later accepts and adjusts to the disease.

2. The family structure and the quality of psychological functioning of the family system at the time of diagnosis. The diagnosis of diabetes in one family member obviously does not occur in a vacuum; appearance of diabetes may be viewed as inserting an additional "stage" in the family life cycle posing problems which require resolution by all family members, as well as to the existing patterns of family interaction.

3. The effect of the diagnosis and living with diabetes on further psychological development (particularly of the child and adolescent) and/or psychological restructuring (particularly in the adult). In the insulin-dependent adult diabetic, the nature of psychological reaction and/or adjustment to complications could be emphasized.

4. The effect of diabetes on reorganization of the family structure and psychological functioning of its members. Particular attention could be focused on changes in patterns of family interaction between specific family members attributable to the presence of diabetes.

5. How the patient's and family's reactions to diabetes affect the management and clinical course of the patient's disease.

6. Psychological aspects of the patient's ability or inability to keep weight under control.

B. Research designs in these areas may wish to utilize one or more of the following approaches:

1. The research plan could encompass different stages of development in the adjustment to diabetes by the patient and family. It could elucidate how the chronic illness is incorporated into the patient's developing identity. Psychological research can address developmental factors of age and sex within the separate populations, i.e., juvenile insulin-dependent diabetics, adult insulin-dependent diabetics, and maturity-onset diabetics. Research could then consider age and sex differences in the adjustment to diabetes and to complications of the disease.

2. Based on available evidence of psychological functioning before onset, studies could measure individual reaction and adjustment to the diagnosis of diabetes. Re-evaluation throughout the course of the disease would then have a measurable predictive value for clinical management of the illness and subsequent psychological reorganization within both the patient and the family. Longitudinal methods of investigation would also allow the study of psychological adjustment to diabetic complications based on the predictive value of earlier psychological adjustment to the previous clinical course of the disease.

3. Research could address psychological issues of family interaction as these pertain to restructuring of psychological functioning in the family, related to the presence of diabetes in one of its members.

4. Such clinically oriented research as has been described above could not only employ standard tests of personality structure, psychological functioning, etc., but could also include techniques of psychological inquiry, based on treatment, to provide an additional base for research assessment. The skills of clinical psychologists and psychiatrists, who are knowledgeable about the biochemical and physiological basis of diabetes, could be used equally in both areas.

II. Training

Since the Diabetes Research and Training Center will most likely be involved in the training of health professionals, it would be appropriate to include approaches and techniques of prevention and intervention which are derived from the findings of diabetes-related psychological research.

Consideration could also be given to a team approach to management, starting at the time of diagnosis. The following health professionals could be included:

1. Medical students; interns and residents, particularly those in the primary care specialties, such as pediatrics, family medicine, and internal medicine.

2. Residents, particularly those in the primary care specialties of pediatrics, family medicine, internal medicine, and psychiatry.

3. Practicing physicians, including but not limited to diabetologists and psychiatrists, through post-graduate education in the form of workshops, symposia and/or audiovisual media, sponsored on a regular ongoing basis. Centers could apply to the AMA for approval as Category I continuing medical education.

4. Allied health professionals, such as social workers, psychologists, nurses, particularly those in physician-extender roles and those with specialized expertise in counseling, and dietitians/nutritionists, through post-graduate education as described in #3 above.

III. Psychological Services (clinical)

If a Center should elect to have such a program as described above, it could serve as a resource and model program for the provision of clinical psychological services to diabetic patients and their families. The following could be included:

1. Initial assessment and counseling at the time of diagnosis, as a means of preventing poor psychological adjustment at a later date.

2. Psychological follow-up of the patient and family at regular intervals for continued assessment and counseling as indicated. (Items 1 and 2 could employ the skills of psychiatric social workers, nurses in extended roles, psychiatrists and/or clinical psychologists).

3. Intervention in the form of individual and/or family therapy by a clinical psychologist or psychiatrist, as indicated by the emotional condition of the diabetic patient and the family. Such intervention could be provided as necessary on both an acute and chronic basis in order to help resolve existing problems of adjustment to diabetes and to strengthen the ability of the patient and family to cope and adjust to the illness.

IV. The Diabetes Centers may include a repository for current information relating to the psychological aspect of diabetes, i.e., literature, audio-visual materials, and records of research in progress elsewhere, for the use of those working at the Centers, as well as those practicing in the community.

APPENDIX C

NATIONAL DIABETES ADVISORY BOARD

PUBLIC LAW 94 - 562

TITLE II—DIABETES

NATIONAL DIABETES ADVISORY BOARD

Sec. 201. (a) Part D of title IV is amended by inserting after section 436 the following new section:

"NATIONAL DIABETES ADVISORY BOARD

"Sec. 436A. (a) The Secretary shall establish a National Diabetes Advisory Board (hereinafter in this section referred to as the 'Board') to be composed of twenty-three members as follows:

"(1) The following ex officio members: The Assistant Secretary for Health or his designee, the Director of the National Institutes of Health or his designee, the Director of the National Institute of Arthritis, Metabolism and Digestive Disease or his designee, the Director of the National Heart, Lung, and Blood Institute or his designee, the Director of the National Eye Institute or his designee, the Director of the Center for Disease Control or his designee, the Administrator of the Health Services Administration or his designee, the Administrator of the Health Resources Administration or his designee, the Associate Director for Diabetes of the National Institute of Arthritis, Metabolism, and Digestive Diseases or his designee, the Chief Medical Director of the Veterans' Administration or his designee, and the Secretary of Defense or his designee.

"(2) Seven members shall be appointed by the Secretary from individuals who are not in the employ of the Federal Government and who are health and allied health professionals or scientists representing the various specialties and disciplines involved with diabetes mellitus and related endocrine and metabolic diseases.

"(3) Five members shall be appointed by the Secretary from the general public, including at least one person with diabetes and two persons each of whom is a parent of a diabetic child.

"(b) The members of the Board shall select a Chairperson from among the appointed members.

"(c) The Secretary shall, after consultation with and consideration of the recommendations of the Board, provide the Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Board, provide the Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Board to carry out its functions.

"(d) Members of the Board who are officers or employees of the Federal Government shall serve as members of the Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board. While away from their homes or regular places of business in the performance of services for the Board, members of the Board shall be allowed travel expenses including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b) of title 5 of the United States Code.

"(e) The appointed members of the Board shall be appointed to serve until the expiration of the Board (as provided in subsection (l)).

"(f) The Board shall—

"(1) review and evaluate the implementation of the long range plan to combat diabetes mellitus (hereinafter in this section referred to as the "Diabetes Plan") formulated by the National Commission on Diabetes under section 3(e) of the National Diabetes Mellitus Research and Education Act, and

"(2) for the purpose of assuring the most effective utilization and organization of diabetes resources, advise and make recommendations to Congress, the Secretary, and the heads of other appropriate Federal agencies with respect to the Diabetes Plan and with respect to the guidelines, policies and procedures of Federal programs relating to diabetes.

"(g) The Board may collect such data as it deems advisable and necessary to enable it to perform the functions required by subsection (f).

"(h) The Board may, from time to time, establish Subcommittees. Such Subcommittees may be composed of Board members and nonmember consultants with expertise in the particular area addressed by such Subcommittees.

"(i) The full Board shall hold regular quarterly meetings. In addition, the full Board or any of its Subcommittees may hold such additional meetings as are necessary in order to enable the Board to carry out its activities.

"(j) One year after the date of its establishment and each year thereafter the Board shall submit to the Secretary and to the Congress a report—

"(1) which describes the Board's activities during the year for which the report is made;

"(2) which describes and evaluates the progress made in such year in diabetes research, treatment, education, and training;

"(3) which summarizes and analyzes expenditures made by the Federal Government for diabetes-related activities during the year for which the report is made; and

"(4) which contains the Board's recommendations (if any) for changes in the Diabetes Plan.

The annual diabetes report shall be made available to the public at the same time it is transmitted to Congress and the Secretary.

"(k) There are authorized to be appropriated to carry out the purposes of this section $300,000 for the fiscal year ending September 30, 1978, $300,000 for the fiscal year ending September 30, 1979, and $300,000 for the fiscal year ending September 30, 1980.

"(l) The Board shall expire on September 30, 1980.".

(b) The Secretary of Health, Education, and Welfare shall establish the National Diabetes Advisory Board (established by the amendment made by subsection (a)) not later than ninety days after the date of enactment of this section.

APPENDIX D

THE PRIVATE SECTOR

Report to the National Commission on Diabetes:

Activities Carried Out By

THE AMERICAN DIABETES ASSOCIATION, INC.

The American Diabetes Association is a national voluntary health agency with 53 Affiliate Associations throughout the country which raise funds to support programs of research, professional education, patient education, and public education and detection. In 1975 the national and Affiliate income reached a new high of more than $7 million; the dramatically continuing expansion of the Association's program activities is evidenced by the following synopsis:

RESEARCH - in 1975, the Affiliates and the national Association invested a record sum of approximately $1.3 million, an increase of 58% over 1974. Although projections for total 1976 research expenditures are difficult, it is anticipated that more than $1.6 million will be allocated by the national Association and its Affiliates. These funds are used to support the Association's three research programs, after peer review by the Committee on Research and approval by the Association's Board of Directors: 1) Established Investigatorships, providing full-time support over a five-year period for two research scientists chosen annually; 2) Research and Development Awards, providing a one-year salary stipend to younger investigators; 3) Research Grants, to provide equipment, supplies, or technical assistance needed to undertake scientific projects. Even with continuing increases in support, the Association is unable to fund many of the approved applications each year. Annually the national Association and many of its Affiliates also conduct Research Symposia so that scientists can explore and evaluate new concepts in the area of diabetes research.

PROFESSIONAL EDUCATION - Annual continuing education courses are conducted by the national Association and by many of its Affiliates, to bring to the entire health care team (physicians, nurses, educators, dietitians, pharmacists, etc.) innovative tools and techniques to be translated into better care, and control and improvement of the quality of life for those with diabetes. It is conservatively estimated that more than 15,000 health care professionals attended these programs in 1975.

In December 1975 the Fourth Edition of Diabetes Mellitus was published under the direction of the Committee on Professional Education. As with previous volumes, the work continues to be recognized as an authoritative text in the management of diabetes and is sold at a low cost to practicing physicians throughout the world.

DIABETES: The Journal of the American Diabetes Association, the only journal in this country devoted each month entirely to publication of scientific reports on diabetes research, is now in its 25th year. To help meet the urgent need to translate advances in diabetes research into improved care for the diabetic, the Association has approved the publication of a second professional journal directed at all members of the health care team. A special committee of the Association is working with the American Nurses Association to develop standards for use in the treatment of diabetic patients.

PATIENT EDUCATION - The Association's magazine for diabetics and their families, DIABETIC FORECAST, has a circulation of more than 100,000 and a projected readership of 350,000 in the United States and 91 foreign countries. The magazine keeps the diabetic up to date on medical advances as well as providing practical information about diet, exercise and medication, and feature articles about individual experiences. The activities of the national Association and the Affiliates are highlighted throughout the year.

In December 1975, for the first time in the magazine's 29-year history, a Special Edition was printed, containing verbatim the first volume of the Report of the National Commission on Diabetes to the Congress of the United States, "The Long Range Plan to Combat Diabetes". In addition to distribution to all FORECAST subscribers, the Special Edition was sent as a public service to each member of Congress and to members of the Congressional staff.

In June 1976, in cooperation with The American Dietetic Association and the National Institute of Arthritis, Metabolism and Digestive Diseases, the

Association's Committee on Food and Nutrition published a new edition of "Exchange Lists for Meal Planning", the first thorough revision of the instructional pamphlet in more than twenty years. The Exchange Lists are a system of food values the diabetic must learn to plan his meals in accordance with his physician's instructions.

Many other patient education pamphlets and brochures, including a programmed course of instruction and a cookbook, are distributed through the Affiliates and the national office. The national office alone receives about 50,000 mail and telephone requests each year from all over the world, as patients with diabetes seek help in living with the disease. Affiliate Associations conduct regular classes to teach their members how to take care of themselves, as well as to provide career guidance, diet advice, and psychological counselling.

One unique way in which young patients with diabetes learn to manage their disease is through 58 special camps for children with diabetes, most under the supervision of Affiliate Associations. In addition to the normal activities of a summer camp, the children learn how to give themselves insulin injections, test their urine, and eat appropriate foods. The Committee on Camps holds annual workshops to encourage continuing refinement of teaching techniques employed at the camps, and is currently working on standards of accreditation for such camps.

PUBLIC EDUCATION AND DETECTION - Publication of the Commission's report provided the first authoritative statistics about the disease since 1968. To provide accurate information to the American public, the "Fact Book on Diabetes" was revised by the Committee on Public Education and is now in distribution, including 5,000 copies ordered by NIAMDD.

The Association's Committee on Statistics is currently working with the National Commission and NIAMDD in preparing a statistical source book on diabetes, based on the Commission's report, which will be published by the government.

The Association continues to work with other organizations, such as The American Association of Retired Persons/National Retired Teachers Association, to educate the public about the disease. "Special publics", such as teachers, firemen and the police are being taught about diabetes through materiials prepared by the Association's Committee on Diabetes in Youth and Committee on Public Education.

Publication of the Commission's report, and the subsequent actions of Congress evaluating the need for additional appropriations and a National Diabetes Advisory Board, have made it apparent to the Association that a very important "special public" is the Congress of the United States. Accordingly, members of the Association have testified before Congressional Subcommittees and have made plans to continue and expand the working relationship between the American Diabetes Association and members of Congress.

The Affiliate Associations conduct detection drives in local communities in an effort to educate the public and find undiagnosed diabetics so they can receive proper medical treatment. Affiliates and the national Association also concern themselves, through Committees on Employment, with the serious problems of discrimination against diabetics which have long existed in business. Similarly, Committees on Insurance work to ensure coverage for those with diabetes; only in the past few years has it been possible for some diabetics to obtain coverage at reasonable premiums.

Copies of the Association's 1975 Annual Report, and all other materials, are available through the Association's Affiliate Associations or at the national office in New York.

WENDELL MAYES, JR.	DONNELL D. ETZWILER, M. D.
Chairman of the Board	President

September 8, 1976

REPORT TO THE NATIONAL COMMISSION ON DIABETES ON ACTIVITIES OF THE JUVENILE DIABETES FOUNDATION

The Juvenile Diabetes Foundation (JDF) is a national voluntary health agency with over 75 chapters in the United States and Canada. JDF is helping to launch a full scale attack on the problems of diabetes with programs of research funding, public and professional education, service to diabetics and their families, as well as cooperation with Congress on legislation and appropriations. These efforts are highlighted in the following summary:

RESEARCH

Eighty percent of the Foundation's total income is allocated to research and postdoctoral fellowship grants. On the basis of a peer review system, research and fellowship applications are rated by a Medical Science Advisory Board and recommended funding is approved by the Foundation's Board of Directors. For the fiscal year beginning July 1, 1976, the JDF has awarded over $1 million to the support of 35 research projects and 9 postdoctoral fellowships, bringing JDF's total research allocation to over $2 million.

SERVICE

The JDF established a national network of patient and parent counseling services to help the newly diagnosed diabetic and their families. Hospitals, schools, clubs, civic and fraternal organizations are also provided with materials, speakers and programs for appropriate health education classes or meetings on the problems on diabetes.

PUBLIC AND PROFESSIONAL EDUCATION

A national educational public service campaign was launched by the JDF through the use of the communications media. Requests for information come to our offices each month and all are filled appropriately. Pamphlets on many aspects of juvenile diabetes are distributed to appropriate audiences. Our quarterly newsletter, "Dimensions", serves as an informational update for both the lay and professional communities. JDF's National Conference brought together a representative cross section of the diabetes community for meetings, workshops and seminars.

White House Meeting

Eighty key representatives from the governmental, private, scientific and philanthropic communities concerned with diabetes met at The White House Conference on Diabetes, May 24, 1976. The day's meeting concluded with unanimous agreement that appropriate action must be immediately undertaken to launch a full scale, coordinated attack on diabetes.

U. S. Congress

The Juvenile Diabetes Foundation has remained active in responding to the needs of individual legislators and their appropriate committees and subcommittees, as interest in and action on this major national health problem accelerates. The report of the National Commission on Diabetes, has alerted Congress to the urgent need for prompt action in helping to implement a long-range plan to combat diabetes. Appropriate legislation was drafted and public hearings held to give all concerned parties an opportunity to be heard. Thus, when on May 11, 1976, hearings were held by the Health Subcommittee of the Senate Committee on Labor and Public Welfare, The Juvenile Diabetes Foundation presented testimony. Subsequently, at the appropriations hearings of both the Senate and the House of Representatives, the Juvenile Diabetes Foundation supplied detailed budgetary recommendations. The significant add-on to support diabetes research and manpower programs, resulting from the Senate and House Conference Committee, as part of the Labor-HEW appropriations bill, is a product of work, negotiation and cooperation between the private and governmental sectors. The JDF was also invited to testify before the House Subcommittee on Health and Environment to consider a bill to establish a National Diabetes Advisory Board.

The Juvenile Diabetes Foundation looks forward to remaining an active and respected informational resource which will continue to be called upon to confer with and advise all groups within the government and the private sector, dealing with any aspect of the diabetes problem.

Maurice Hertzfeld Chairman of the Board of Directors	Carol Lurie President

THE JUVENILE DIABETES FOUNDATION
23 East 26th Street
New York, New York 10010

AMERICAN FOUNDATION FOR THE BLIND, INC.
15 WEST 16th STREET
NEW YORK N. Y. 10011

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Report of the National Commission on Diabetes to the Congress of the United States: The

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DISCRIMINATION PROHIBITED: Under provisions of applicable public laws enacted by Congress since 1964, no person in the United States shall, on the ground of race, color, national origin, sex, or handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. In addition, Executive Order 11141 prohibits discrimination on the basis of age by contractors and subcontractors in the performance of Federal contracts. Therefore, the National Commission on Diabetes must be in compliance with these laws and executive order.

DHEW Publication No. (NIH) 77-1230